Does the Iranian health system need a Health Technology Assessment programme to improve effectiveness, efficiency and equity of its healthcare services?

Thesis submitted in accordance with the requirements of the University of Liverpool for the degree of Doctor of Philosophy by:

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DECLARATION

This thesis has been written exclusively by the PhD candidate, Majid Davari Dolatabadi. At no previous time was this work submitted for a degree.

All quotations have been distinguished by quotation marks and sources of information acknowledged.

Majid Davari Dolatabadi

DEDICATION

For my wife Zahra Rabbani and my children Farzaneh and Fazel, without whose love and support the completion of this thesis would not have been possible.

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Majid Davari Dolatabadi

ABBREVIATIONS

AFMSIO	Armed Forces Medical Services Insurance Organisation
BCG	Bacilli Chalmette Guerin
CT	Computer Tomography
DES	Diethylstilbestrol
DoH	Department of Health
EBM	Evidence Based Medicine
EEE	Effectiveness, Efficiency, Equity
E&W	England and Wales
FAD	Final Appraisal Determination
FDD	Food & Drug Department
FFS	Fee For Service
GDP	Gross Domestic Product
GDG	Guideline Development Group
HIC	High Insurance Council
HIO	Health Insurance Organisation
HN	Health Network
HTA	Health Technology Assessment
HTACB	Health Technology Assessment Commissioning Board
IBTO	Iranian Blood Transfusion Organisation
ICER	Incremental Cost-Effectiveness Ratio
ICHI	Imdad Committee Health Insurance
ILNA	Iranian Labors News Agencies
INN	International Nonproprietary Names
IRCS	Iranian Red Crescent Society
IRNA	Islamic Republic News Agency
ISC	Iranian Statistical Centre
ISNA	Iranian Students News Agency
M&PO	Management and Planning Organisation
MH&ME	Ministry of Health & Medical Education
MP	Member of Parliament
MRI	Magnetic Resonance Imaging
MSIO	Medical Services Insurance Organisation

NA	Needs Assessment
NCC	National Collaborating Centre
NCCHTA	National Co-ordinating Centre for Health Technology Assessment
NGO	Non-Governmental Organisation
NHS	National Health Service
NICE	National Institute for Clinical Excellence
OTC	Over-The-Counter
PCHE	Per Capita Health Expenditure
PCSO	Producer Consumer Supporting Organisation
PCT	Primary Care Trust
PHC	Primary Health Care
PHN	Primary Healthcare Network
POD	Prescription-Only Drug
PSG	Prioritization Strategy Group
RCT	Randomised Controlled Trial
RHA	Regional Health Authority
RHC	Rural Health Centre
RIS	Rural Insurance Scheme
SHA	Strategic Health Authority
SID	Supplier-Induced Demand
SSIO	Social Services Insurance Organisation
STA	Single Technology Appraisal
TA	Technology Assessment
TAIL	Technology Assessment Iterative Loop
TAR	Technology Assessment Review
UHC	Urban Health Centre
WHO	World Health Organisation
WO	Welfare Organisation

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ABSTRACT

Does the Iranian health system need a Health Technology Assessment programme to improve effectiveness, efficiency and equity of its healthcare services?

Background
Health Technology Assessment (HTA) is increasingly being utilized on a global scale to improve the clinical and cost-effectiveness of healthcare resource utilization. This thesis addresses the potential application and implications underlying the development of a structure of HTA specifically designed to fit in with the culture and healthcare system in Iran.

Aims
The aims of this thesis were threefold. Firstly, to undertake a detailed analysis of individual aspects of the Iranian healthcare system to identify the nature and context in which the system of HTA would be applied. In particular, aspects of the culture of the healthcare system that would promote or discourage the use of HTA in Iran are evaluated in detail.

The second aim was to undertake a detailed analysis of how HTA works in practice. Given that the HTA system in England and Wales is one of the most well developed, it was decided to focus on this national system. The aim of this aspect of the thesis was to develop a detailed understanding of how HTA works in practice and how it is best embedded into national structures of healthcare decision-making.

The third aim was to assess the extent to which the culturally sensitive introduction of HTA to Iran would assist in achieving the objectives of the Iranian healthcare system.

Main findings and conclusions
Very little published information is available concerning the various aspects of the Iranian healthcare system. As a consequence, the majority of the information gathering was undertaken through interviews with key strategic and operational decision-makers to unlock their knowledge concerning the challenges faced by the Iranian healthcare system.

The interviews identified a range of specific elements that would be crucial in designing and implementing a system of HTA for Iran. The potential strengths and limitations of such a structure are explored in detail. Perceived advantages of implementing HTA in Iran would include the enhanced development of clinical guidelines and enhanced control of new health technologies. In addition, it would require policy-makers to explicitly address the policy trade-off at the heart of the Iranian healthcare system.

CHAPTER 1

INTRODUCTION

1 INTRODUCTION

1.1 Aim and structure of the thesis

The broad research question being addressed in this thesis is whether health technology assessment is of any value in improving resource allocation within the specific context of the Iranian healthcare system. Addressing such a broad question inevitably raises a series of specific aims and objectives that need to be analysed to help address this issue. These specific aims and objectives include:-

1. Providing a detailed description of what is meant by 'health technology assessment'
2. Outlining the difficulties involved in undertaking research and evaluating the potential contribution of HTA in a research naïve environment such as Iran
3. Providing a detailed description of the health service context into which HTA would be introduced and evaluating in detail the implications of this context for HTA
4. Identification of the objectives of the Iranian healthcare system in terms of efficiency, effectiveness and equity
5. Evaluating the potential value of different structures of HTA in improving the ability of the Iranian healthcare system to achieve its objectives
6. Making practical recommendations concerning the introduction of HTA in Iran

To effectively assess the potential value of HTA to Iran, the first step is to develop a detailed understanding of what is meant by 'health technology assessment' and its relationship to the associated disciplines of evidence-based medicine and health economics. As such, in Chapter 2, a review of the history and background to HTA is undertaken. The development, reasons and philosophy underlying technology assessment are assessed, together with the growing importance of evidence-based medicine (EBM).

In addition, the development of health economics as a sub-discipline of economics in response to economic pressures on health systems is assessed. Finally, the philosophy of HTA and its approach to healthcare services is discussed, together with the range of challenges in methodology, performance, impact and acceptance of HTA are reviewed. The role of ethics in the process of decision-making in the field of HTA is also addressed in Chapter 2.

The next requirement is to outline how in a research-naïve environment such as Iran the necessary evidence can be generated to make meaningful statements concerning the potential applicability of HTA. The theoretical structure and methodology of the study is therefore described and explained in Chapter 3. The needs assessment methodology and the details of the qualitative method utilised, including the selection of key informants, method of interviewing, extraction of data and analysis of the interviews are also explored and clarified in Chapter 3.

For health technology assessment to be effective, it is necessary to adapt and integrate it into the culture, structure and resource availability of its host health system. The socioeconomic conditions of the country being analysed therefore represents a fundamental determinant of the resources available to fund HTA. The first part of Chapter 4 therefore addresses the impact of Iran's economy on the socioeconomic circumstances of Iranian society and government over the past 30 years. Chapter 4 also provides a comparison between Iran and other economies to place Iran into an international context. The relationship between population and development is demonstrated by many studies ((ICPD) 1994). There is also a strong link between the age structure of the population, healthcare needs, and healthcare utilization (Murray CJL and Julio 1999). The growth rate, the nature, and the distribution of the Iranian population are therefore also described in detail in the first part of Chapter 4. The implications for HTA on the healthcare delivery system in Iran is evaluated in the second part of Chapter 4 through an analysis of the structure, organisation and background of the Iranian health system. The method of healthcare management and financial distribution of healthcare resources

is also reviewed in this part of Chapter 4. Given the paucity of published information, a wide range of interviews were undertaken with key decision-makers. The results of these interviews are presented in two main sections in Chapter 4. The first part explains the main achievements of the Iranian health system from interviewees' points of view. The most important challenges for the health system are then considered in next section. This chapter ends with an extensive analysis of the results of the interviews.

In addition to the structure of healthcare, the methods of financing healthcare will fundamentally determine the value and applicability of HTA. In a largely fee-for-service system such as the United States, it is arguable that HTA is of much more limited applicability. In such systems, services respond to demand rather than clinical need and are rationed by ability to pay with the price system providing the invisible hand that allocates resources within the health system. Conversely, in a system such as the British NHS that is publicly funded, free at the point of delivery and responding to need rather than demand, a mechanisms such as HTA is vital in rationing and allocating resources to areas of greatest clinical need. As such, the role of health insurance in promoting population health is very important (Cutler and Zeckhauser 1999) especially in welfare-oriented Bismarck-type health systems (Roemer 1991) like Iran. Chapter 5 discusses health insurance organisations and their functions in Iran, covering the four main health insurance organisations in Iran, their covered population, and their financial policies. The interviews, analysis and conclusions regarding health insurance are provided in Chapter 5.

Pharmaceuticals play an important role in healthcare systems across the world and represent an important focus for HTA policies (Walley, Haycox et al. 2004). Analysis of pharmaceutical policy and pharmaceutical regulations will be discussed in chapter 6. In the light of the results of the interviews and their analysis, the impact of the challenges and difficulties facing Iran at the present time are discussed in detail.

In the final part of the study, the third step of the needs assessment analysis is presented. In Chapter 7, a potential structure of health technology assessment for Iran is developed and discussed and available policy options for the appropriate utilization and goals of the HTA programme are examined in detail. Finally, Chapter 8 provides broad conclusions and a range of recommendations relating to the applicability and value of HTA in Iran.

1.2 Health Technology Assessment – is it applicable to Iran?

Health is a complex issue ((IOM) 2000) and healthcare is perhaps the most complex industry in the world (Smith, Ginnely et al. 2005). Health is, also, a valuable commodity and good health is one of the primary needs of human beings. Health services have evolved over a long period to maintain and to improve the health status of human societies. Health services have faced a wide range of challenges in recent decades. Demand has expanded due to expensive treatments and technologies, aging populations and increasing public demands and expectations (Carlsson, Hultin et al. 1998); (Henderson 1999); (Walley, Haycox et al. 2004); (Donaldson, Gerard et al. 2005). The root of these challenges lies in the mismatch of enhanced demand for healthcare on one hand, and the limitations on available resources on the other. It is clear that there will never be sufficient resources to achieve all ideal objectives in health care, even for rich countries. Optimisation of the use of resources and cost containment has, therefore, become one of the first priorities of health systems worldwide (Banta and Vondeling 1994); (Walley, Haycox et al. 2004); (Donaldson, Gerard et al. 2005). An inherent part of achieving this objective has been the aim of establishing and effectively implementing a process of technology assessment in the field of healthcare. Establishing such a system requires society to build links between the science of health care and health policy (Carlsson, Hultin et al. 1998).

Health Technology Assessment (HTA) is the scientific and evidence-based evaluation of health technologies. It identifies the clinical and cost-

effectiveness of new health technologies and compares their Incremental Cost-Effectiveness Ratios (ICERs) with other health interventions in the same therapeutic area. The aim of HTA is to identify and promote the use of clinically and cost-effective interventions and to minimise the use of interventions whose benefits do not appear to justify their costs. In this manner, scarce health resources can be targeted upon structures of health interventions which provide the greatest overall benefit to society.

Health Technology Assessment programmes and organisations have eveloped, mainly in advanced countries, to reduce utilization of ineffective healthcare technologies and to enhance utilization of effective healthcare technologies and in this manner, to assist health policy makers to optimise resource allocation in order to obtain better value for money (Banta and Vondeling 1994). The effectiveness, efficiency and equity (EEE) criteria provide a broad perspective, grounded in relevant theory and research, for assessing the performance of health policies and programmes in achieving these overall healthcare system goals (Aday, Begley et al. 1999). These criteria are often, but not always complementary. Encouraging the use of more effective healthcare technologies via HTA, therefore, can help health decision-makers to provide services more efficiently. Rationalizing uses of resources to achieve efficiency may also provide the opportunity to extend effective services more widely to underserved population groups and thus improve equity in access to healthcare services. Improving healthcare effectiveness also provides opportunities to increase both efficiency and equity. It is important to note, however, that the objectives of EEE may also be conflicting in certain cases (Donaldson and Gerard 2004); (Walley, Haycox et al. 2004). That is, it may be necessary to forego a certain level of the efficiency to improve equity or some level of equity may have to be sacrificed to achieve improvements in efficiency. In addressing and analysing such trade-offs, HTA represents a key tool in improving the management of limited health care resources (Banta and Perry 1997). This thesis focuses on the possible applicability of HTA to Iran. To evaluate this requires a detailed understanding of the health service system in Iran.

The health system in Iran has faced many changes and challenges in recent years. The introduction of new and expensive technologies has increased its health expenditures sharply (Table 4.3) and in addition to such general pressures, the Iranian health system has also faced considerable social and economic changes and challenges in the past thirty years which have impacted on the Iranian health system directly or indirectly. The 1979 revolution, the eight-year war against Iraq, rapid increase in the size of the Iranian population, economic sanctions and the immigration of around four million Afghan people during their civil war all imposed significant strains on the Iranian health system in recent decades.

The hypothesis behind this thesis is whether, given that HTA programmes have been successfully implemented in a number of health systems, such a system can help the Iranian health system to improve its healthcare resource utilization. Furthermore, the benefits derived through the implementation of a HTA programme on a system with more restricted resources and increasing demands on healthcare services may be even greater than what has been achieved in advanced countries. It is important to acknowledge, however, that the success of such a programme or a policy depends on many factors. A successful programme or policy in one country cannot necessarily be transferred with equal success to other countries. HTA programmes are no exception and therefore the appropriateness of any structure of HTA requires evaluation in the individual context of the country in which it is being applied/envisaged.

In addition, even where a HTA programme would potentially improve resource allocation, the question remains whether such a programme of HTA is acceptable to the population being served and adequately reflects the values and expectations of Iranian society. It is important to note that despite the similar aims and objectives of HTA programmes in various countries, their organisational structure, process of assessment, and methods of implementation vary significantly (Hailey 1994); (Spiby

1994); (Orvain, Xerri et al. 2004); (Stevens and Milne 2004). In addition, HTA programmes have had variable levels of acceptance in their implementation in different countries (Battista, Jacob et al. 1994) with a crucial element of successful implementation being attributed to differences between health systems (Banta and Vondeling 1994) and the extent to which HTA is in tune with the broader cultural context in which the HTA system is being implemented. As the role of HTA expands, it is inevitable that the cultural context becomes more important (Battista 2006). For these reasons, it is essential, therefore, to consider the specific Iranian context with regard to the structure of health systems as well as its unique economic, social, and environmental conditions.

Given the need for cultural sensitivity, it is clear that it is not sufficient to simply copy one of the current HTA programmes and apply it in the Iranian context. HTA is a systematic interdisciplinary process based on scientific evidence and other types of information (Banta and Vondeling 1994). Thus, although the experiences and outcomes of countries with existing HTA programmes will provide essential evidence and experience in establishing an Iranian-specific programme, adequate attention must also be paid to the specific requirements of their health systems as a whole.

It is also important to address the issue of affordability and cost-effectiveness in implementing HTA programmes. HTA programmes are themselves not costless and just as resources are limited for healthcare services they are equally restricted in implementing HTA programmes. Thus it is important to assess, in advance, if a HTA programme is cost-effective in the context of a specific health system by performing a needs assessment to assess the potential cost and effectiveness of HTA applied in a specific context.

1.3 Effectiveness, efficiency and equity within the Iranian healthcare system

The first part of this study aims to analyse the performance of the Iranian healthcare system with respect to the objectives of effectiveness, efficiency and equity. There has been no such study previously published. These three elements are selected for a number of reasons. Firstly, because they provide a broad perspective, grounded in relevant theory and research, for assessing the overall performance of health policies and programmes in achieving the goals of clinical effectiveness, cost containment, and equity of access, (Aday, Begley et al. 1999). Secondly, they are closely connected with the HTA objectives of optimising the use of resources and targeting healthcare on more efficient health technologies (Tugwell, Bennett et al. 1985); (Feeny, Guyatt et al. 1986); (Jacobs and Rapoport 2004); (Walley, Haycox et al. 2004) to achieve significant health improvement (effectiveness), the optimum use of scarce resources (efficiency), and the distribution of benefits and costs fairly across groups (equity).

Effectiveness evaluates the benefits of healthcare intervention measured by improvements in health (Aday, Begley et al. 1999) and examines the ability of healthcare systems or intervention to achieve stated goals or objectives. In the health context, the relationship between interventions and health outcomes are considered as effectiveness. Effectiveness is, also, a measure of the ability of an intervention to bring about an outcome in real-world clinical practice (Jacobs and Rapoport 2004), in contrast to efficacy, which refers to the ability to bring about an outcome under the ideal conditions of the clinical trial.

Efficiency relates health improvements to the resources required to produce them (Aday, Begley et al. 1999) and represents the ratio of the output to the input of any system. Efficiency is divided into "technical" and "economic or allocative" efficiency. Technical efficiency measures how a given combination of resources is utilised to produce a maximum amount of output. Allocative efficiency measures the extent to which resources

are combined optimally to yield maximum consumer satisfaction (Jacobs 1997); (Walley, Haycox et al. 2004). In addition to technical and economic efficiency, Donaldson defined social efficiency as minimising the cost to society of achieving intended benefits, i.e. minimising opportunity cost (Donaldson and Gerard 2004) which is defined as the benefit forgone when selecting one alternative over the next best alternatives (Haycox, Boland et al. 2004).

Equity is concerned with health disparities and fairness and can be divided into equity in the finance of the healthcare and equity access of healthcare. Each of these concepts are also divided into vertical and horizontal equity and equity in the outcome of healthcare. Financial equity requires each member of society to be allocated the same amount of healthcare resources (cost per capita) irrespective of their need for healthcare.

Equity in access requires services to be provided in such a manner as to provide each member of society with an equal ability to access such services – irrespective of actual structures of service utilisation. Equity of outcome evaluates the extent to which the health experience of each individual member of society varies from the norm.

Vertical equity in utilisation of healthcare is defined as persons in unequal need, should be treated in an appropriately dissimilar way. Horizontal equity in delivery of healthcare means persons in equal need should be treated equally (Van Doorslaer, Wagstaff et al. 1993). In practice, the ultimate test of the equity of health policy is the extent to which disparities or inequalities in health persist among subgroups of the population. Substantive equity is reflected in minimizing subgroup disparities in health. Procedural equity refers to the extent to which the structure and process, or procedures, for achieving these outcomes are judged to be fair. Equity of healthcare is essentially concerned with the operation and performance of the distribution of services (procedural equity). Equity of health encompasses both the medical and non-medical determinants of health and focuses on minimizing disparities in health

across groups within a population – the notion of substantive equity (Aday, Begley et al. 2004).

Maximizing effectiveness by allocating additional resources may conflict with efficiency, if the cost of the resources is high relative to their effectiveness. Maximizing effectiveness and efficiency by distributing resources to persons who would gain the most, may be unfair in terms of procedural equity if the policy leads to an uneven distribution of healthcare utilisation. Identifying the appropriate trade-off between efficiency and equity is, therefore, one of the most important issues that health policy makers need to address (Aday, Begley et al. 2004); (Walley, Haycox et al. 2004). Health services research on effectiveness provides evidence on what medical and non medical interventions result in the greater health improvements. Efficiency studies compare the costs and benefits of producing these improvements given constrained resources; and equity analyses provide guidance for assessing whether both the investment and outcomes in terms of health are distributed fairly. Such issues are addressed in greater detail in Chapter 3.

1.4 What is HTA and is it applicable to Iran?

Before evaluating whether the Iranian health system needs a HTA programme, it is necessary to understand HTA, its nature, its background and its potential costs and benefits. The HTA system in England and Wales is examined to see how a HTA system, commonly perceived as being the most highly developed, works in practice. In addition, HTA in the UK has existed for some time and therefore the range of costs and benefits that arise from it are becoming more apparent.

The main elements of the UK HTA programme are reviewed in detail in Chapter 7. In the chapter, a detailed analysis is undertaken of the nature of the underlying health system, the process of evaluation, the methods of financing, and the process of implementing the results of the evaluation into mainstream clinical practice.

The third part of this thesis combines and integrates the results of the first two parts of the study (Rouda and Kusy 1995) to identify the extent to which a HTA programme can provide an appropriate structure to assist in confronting the challenges faced by the health system of Iran. As discussed earlier, the Iranian health system has been forced to confront many exogenous shocks which have significantly affected the structure and nature of its health services. Such shocks (including revolution, war and sanctions) have placed unique demands on Iranian society. The main aim of this study is therefore to assess whether and to what extent a HTA programme could improve the resource utilization of the Iranian healthcare system and develop its services in terms of effectiveness, efficiency and equity. If this should prove to be the case, what kind of the programme would be appropriate for Iran? What are the potential advantages, challenges, obstacles and opportunities in implementing such a programme in Iran?

This study is designed in four parts; the logic of this method is based on the stages of a needs assessment. A Needs Assessment (NA) provides information about what services are required and how they might best be delivered. It represents a systematic exploration of the gap between current levels of performance and the levels of performance that should be achieved (Stout 1995). In addition, needs assessment can also be used for ranking needs according to how serious, neglected, or salient they are (Rossi, Lipsey et al. 2004). Undertaking needs assessment, therefore, enables the managers of the system to prioritise and understand the needs of the system in order to progress more efficiently (Soriano 1995). The processes of NA are discussed in greater detail in Chapter 3. The first step is to assess the current performance of the system against selected standards. It is necessary to construct and describe a precise definition of the "problem" and assess its extent (Rossi, Lipsey et al. 2004), before defining and identifying the targets of any potential HTA programme for Iran. This analysis would determine the main challenges of the system and the main constraints confronting health policy-makers in the system. Such an analysis would identify where

HTA would fit into such a system. The gap between the current and the desired states identifies what the system needs to achieve its goals effectively (Rouda and Kusy 1995). Therefore a detailed analysis of the Iranian health system is necessary to identify the current challenges and obstacles to the development and implementation of HTA confronting healthcare policy-makers in Iran.

The second step in NA is to identify the underlying causes of the current problems facing the use of new technologies in healthcare in Iran. Problems may arise from methods of financing healthcare, mismanagement of health technologies, or inequitable distribution of health services. The first two parts of this NA are discussed in detail in Chapters 4-6 where there is a detailed analysis of the Iranian healthcare system.

The third step in NA is to identify possible solutions for the problems (Rouda and Kusy 1995). Considering the cause(s) of the problems, can HTA contribute as a possible solution to some of these problems? It is recognised that HTA does not represent a universal panacea to solving all of the problems being experienced and challenges being faced by the Iranian healthcare system. The Iranian system has been confronted by a uniquely challenging set of circumstances (war, revolution, etc) which require a broad set of responses. However, the aim of this thesis is to assess the extent to which HTA can assist Iranian decision-makers to confront such challenges and if so, what would be required to run a HTA system effectively? This step is discussed initially in Chapter 2 and in greater detail in Chapter 7. The review of HTA in England and Wales contained in Chapter 7 helps to understand the advantages and challenges of such a system in practice. Familiarity with the difficulties confronted in the UK could help other healthcare systems to avoid the same problems or at least to prepare for them.

In Chapter 8, the fourth step in NA is undertaken; how to apply the solution. In this part, the potential HTA and its requirements in macro, med and micro levels are discussed and potential barriers and advantages

are also examined. In order to evaluate the appropriateness of the UK model to Iran, a Comparative Contextual Analysis between Iran and the UK is undertaken. Comparative Contextual Analysis is a methodology for comparative research where contextual interrogation precedes any analysis of similarity and difference (Iversen 1991). The Context is a group of individuals or settings in which the subject is to work (Iversen 1991); (Feldman 1999). In this study, therefore, the context of a HTA system is the health system and its stakeholders. With the help of Comparative Contextual Analysis, similarities and differences between the context of Iranian Health System and England and Wales (E&W) Health System are discussed in Chapter 7 while in Chapter 8 the study addresses the extent to which such a model is appropriate to the Iranian health system.

CHAPTER 2

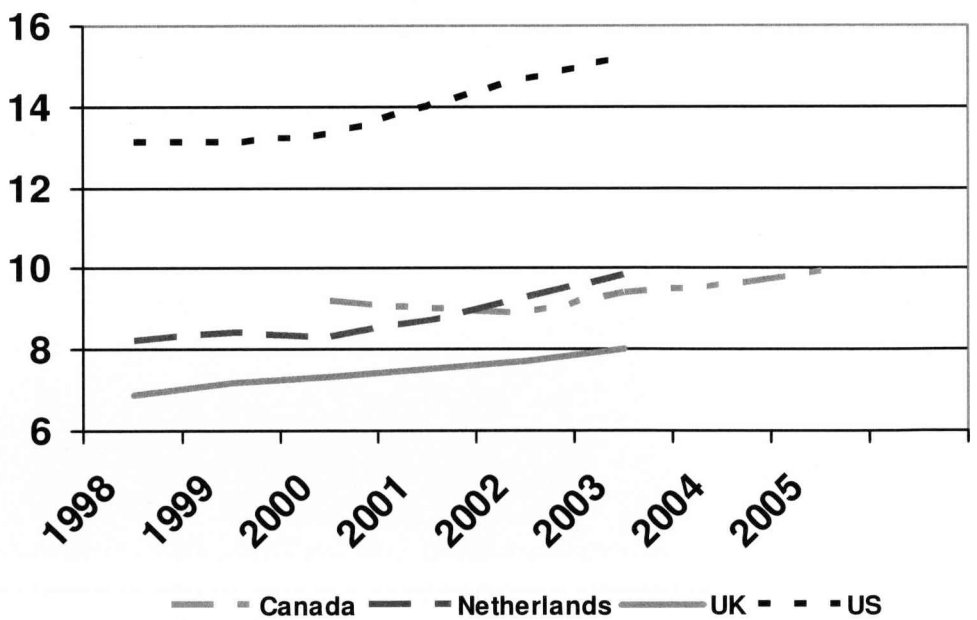
HEALTH TECHNOLOGY ASSESSMENT METHODS AND STRUCTURES

2 HEALTH TECHNOLOGY ASSESSMENT

2.1 Introduction

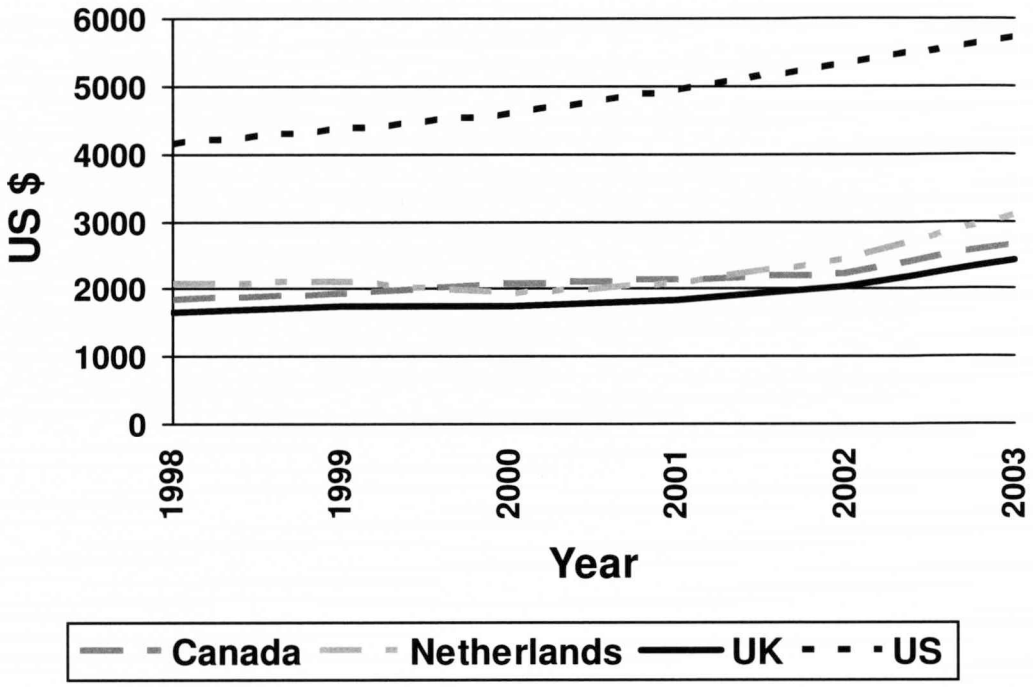
Concerns about the effectiveness of healthcare services and health technologies have been a vital issue from the beginning of the 19th century (Cochrane 1971) although the main diseases and the lifestyle and economic status of societies have changed significantly since this time. The availability of new and expensive technologies has also increased significantly in recent decades leading healthcare expenditures to increase dramatically both as a percentage of GDP (Figure 2.1) and also in terms of per capita expenditure (Figure 2.2).

Figure 2.1 Healthcare expenditure in selected countries as percentage of GDP



Data source: World Bank 2005

Figure 2.2 Per capita healthcare expenditure in selected countries



The increased abundance and diversities of new health technologies have made it more difficult for health policy makers to identify effective interventions in healthcare. Evidence Based Medicine (EBM) is a concept developed mainly to promote the quality of medical care by the identification and application of the best available evidence to support clinical practice. It has extended into the development of evidence-based clinical practice guidelines and more recently to inform resource allocation decisions about medical care (Grayson 1997).

The resources available to fund healthcare are limited in all countries. This raised concerns about the effects of cost control strategies, at a time of rapidly accelerating health expenditures on clinical outcomes (Feeny, Guyatt et al. 1986). It was important, therefore, to identify and adopt not only the most clinically effective healthcare interventions, but also the most cost-effective interventions. As healthcare expenditures increased, the issues of efficiency and equity became more important. Health Technology Assessment (HTA) emerged in 1975 in response to the need to help decision-makers to decide which new technologies were worth

purchasing (Banta and Luce 1993). Since this time, HTA is playing an increasingly important role as a key tool to improve the management of limited health care resources (Banta and Perry 1997). However, it is also important to acknowledge that HTA, as a formalized set of activities, does not have a very long history.

This chapter provides a brief overview of technology assessment in general (Section 2.2) before analysing in greater detail the history, philosophy, and development of health technology assessment worldwide. In order to identify relevant and appropriate materials on this topic a range of key electronic databases including MEDLINE, EMBASE, and Google Scholar were searched using the search terms outlined below and applied to the subject indexing, title, abstract and keyword fields:

Health economics; economics of health, assessment; appraisal; health technology; medical technology; health technology assessment; evidence based medicine; history; and philosophy.

Specific key words and combination of terms were used to narrow down the quantity of literature identified. This was supplemented by "Snowballing" in which further articles of relevance were identified from the related articles. Only English language articles were considered.

2.2 The history of technology assessment

Though technology has a long history in human societies, technology as an applied science only started to play an important role in human societies from the early 1960s (Teich 2005). At the same time, concerns and questions about its social and environmental impacts were increasingly being raised with regard to undesirable consequences of technology such as technological unemployment, toxic pesticides, pollution, auto effluents, forest depletion, resource exhaustion, radioactive waste disposal, electronic invasion of privacy, and climate change (Carpenter 1977).

The concerns were such that the rate of technological change was threatening to exceed the number of talented people necessary to plan and direct its course with some degree of wisdom (Congress 1967). It was felt that some sort of "early warning" was needed. Technology assessment began, therefore, formally in 1965 in the Committee on Science and Astronautics of the House of Representatives in the USA as a process of examining technology and its impacts (Congress 1966); (Assessment 1976); (Banta and Behney 1981[a]). Although the initial focus was on the undesirable consequences of technology, however, one year later Daddario defined Technology Assessment in a more positive manner as "a form of policy research which provides a balance appraisal to the policy maker" and "a method of analysis that systematically appraises the nature, significance, status, and merit of a technological programme" and finally "technology assessment is designed to uncover three types of technology consequences; desirable, undesirable, and uncertain". In addition Daddrio characterized TA as "a system to ask the right questions and obtain correct and timely answers" (Congress 1967). It is notable that while Daddario's definitions highlighted the policy analysis role of TA, others emphasized the evaluative role of TA. Coates defined TA as "the systematic study of the effects on society that may occur when a technology is introduced, extended, or modified, with special emphasis on the impacts that are unintended, indirect, and delayed" (Coates 1971). The US Congress characterized TA as "the analysis of the potential or actual impact, both beneficial and deleterious, of a proposed ongoing, or completed technological development, including the analysis of alternative technological possibilities" (Congress 1972).

Over the years, expectations and perceptions of workers in the field of TA have changed gradually. Ten years after the launch of TA in the US, the president of the international society for technology assessment, stated that "in the first years, emphasis was on TA as an early warning system, on possible detrimental impacts. But now TA is applied to identify and evaluate alternatives of making informed decisions. Coast expressed the view that "I prefer to think of TA as a craft; A craft seeks to combine

creativity (art) with objectivity (science) to produce something useful" (Coates 1976).

Technology assessment, therefore, was developed to provide anticipatory control on technology (Harman 1976) which can reduce the negative impacts of new or modified technologies (Carpenter 1977) and aims to facilitate a rational planning process of technology application.

2.3 Healthcare technologies

2.3.1 Introduction

The application of healthcare technologies to improve the quantity and quality of life experienced by patients has become an essential part of the healthcare systems in modern societies. It is difficult to imagine a health system without high technology therapeutics, devices, medicines, and diagnostic and surgical instruments. Healthcare technology has been defined as "the drugs, devices, medical and surgical procedures used in healthcare, the organizational and supportive systems within which such care is provided" (OTA 1978).

Banta and Luce divided the history of medical science and healthcare technology into three periods. The *Early Period* was characterised by the slow accumulation of medical knowledge through description and empirical observation. This period started with the ancient Greeks and ended with the beginning of modern scientific thought as described by Descartes. The second is the period of relatively *Rapid Development of Knowledge* that occurred between 1800s and the early 1900s. The third period is named the *Modern Era* and is characterised by the biological revolution, the development of machine-based technology, and the increasing prevalence of chronic diseases associated with ageing (Banta and Luce 1993).

Prior to any detailed analysis of HTA, it is necessary to classify health technologies. Feeny and his colleagues classified health technologies by their use, their form, and their embodiment degree (Feeny, Guyatt et al.

1986). Diagnostic, therapeutic, supportive, and organisation technologies are examples of classifying health technologies by use. By form, health technologies can be classified as drugs, devices, and procedures (Banta and Behney 1981[a]). The third method of classifying health technologies is by size and degree of embodiment. According to this classification, a new technology is an embodied technology if it includes a new machine. Computed Tomography (CT) scanners and Magnetic Resonance Imagination (MRI) are examples of embodied health technologies. If the technology is an idea or a procedure that is available without obtaining a new machine or drug, it is considered to be disembodied technology (Feeny, Guyatt et al. 1986). The fourth method of health technology classification is categorizing heath technologies according to their medical purposes and physical nature (Banta and Luce 1993). According to this method, Medical Purposes Technologies and Physical Nature Technologies can be divided into a number of sub-classifications. Table 2.1 summarises various methods for classifying health technologies.

Table 2.1 Various methods of Health Technologies' classification

Category	Subdivision	Example
Usage	• Diagnostic • Therapeutic • Supportive • Organisation Technologies	• Medical tests • Drugs • Vitamins • NICE
Form OR Physical Nature	• Drugs • Devices • Procedures	• Antibiotics • Surgical therapy • Appendectomy
Size	• Embodied Technologies • Disembodied Technologies	• CT Scanner, MRI, Gama Knife • Surgical methods •
Medical Purpose	• Diagnostic • Preventive • Therapeutic • Rehabilitative • Organizational/administrative • Supportive	• Medical tests • Vaccines • Drugs • Medical breast and corsets • NICE • Vitamins

It is clear from the table that classifications by 'Usage' and by 'Medical Purpose' are very similar.

2.3.2 History of Health Technology Assessment

Treatment with herbal medicines and natural drugs were widespread in the early period. Recognition of disease as a part of physical nature by Hippocrates, the 'father of modern medicine' represented a crucial step toward modern medical sciences. The development of human anatomy and physiology in 16th century also provided crucial steps in achieving a better understanding of human disease (Sigerist 1970 (Copyright 1932)); (Reiser 1978). The classification of disease was another important development in the field of disease diagnosis and although this was

suggested by Thomas Sydenham in the 17th century it did not gain widespread acceptance until the 18th century (Sigerist 1970 (Copyright 1932)).

The Cartesian paradigm developed in the 17th century had a significant impact in moving towards modern sciences and technology. One of the important Descartes' principles in this case was separating mind from body and studying the biological organism as a mechanism or machine (Wulff, Pedersen et al. 1986). Because of the power of this Cartesian paradigm, Thomas characterised the 17th century as "the emergence of a new faith in the potentialities of human initiative" (Thomas 1971). The growth of medical diagnostic tools was the other health technology that contributed fundamentally towards the development of medical sciences. Developments of the thermometer in early 1700s, the microscope in the 18th century, the ophthalmoscope in 1850, the laryngoscope in 1857, the blood pressure cuff in 1876, and the cardiograph in 1901 were among notable new diagnostic technologies contributing substantially to medical science (Reiser 1978).

Vaccination made great strides in preventing communicable disease in the 18th and 19th centuries, epitomised by the first usage of cowpox to prevent smallpox in 1796 by Edward Jenner), and vaccine production by Louis Pasteur in the 19th century. The isolation of viruses in 1935 and their subsequent growth in cell culture made possible the development of vaccines for poliomyelitis, measles, rubella, and influenza. Developments in bacteriology and narcotics facilitated the development of modern surgery (Sigerist 1970 (Copyright 1932)).

Pharmacological advances progressed less rapidly. The first pill machine was developed in the 18th century, pill coating began in 19th century and the first syringe was introduced in 1852. Sterile fluids in glass ampoules for subcutaneous injections were introduced in 1886. Multiple dose injection vials were developed in 1922, when insulin became available. The first pharmaceutical aerosol was introduced to the market in 1950 followed two years later by the introduction of sustained release drugs

(Krowczynski 1985). Improvements in pharmaceutical technologies were closely related to growth and improvement in other fields of science. Developments in organic and inorganic chemistry in the 18th century had an inevitable impact in stimulating the development of pharmaceutical technologies.

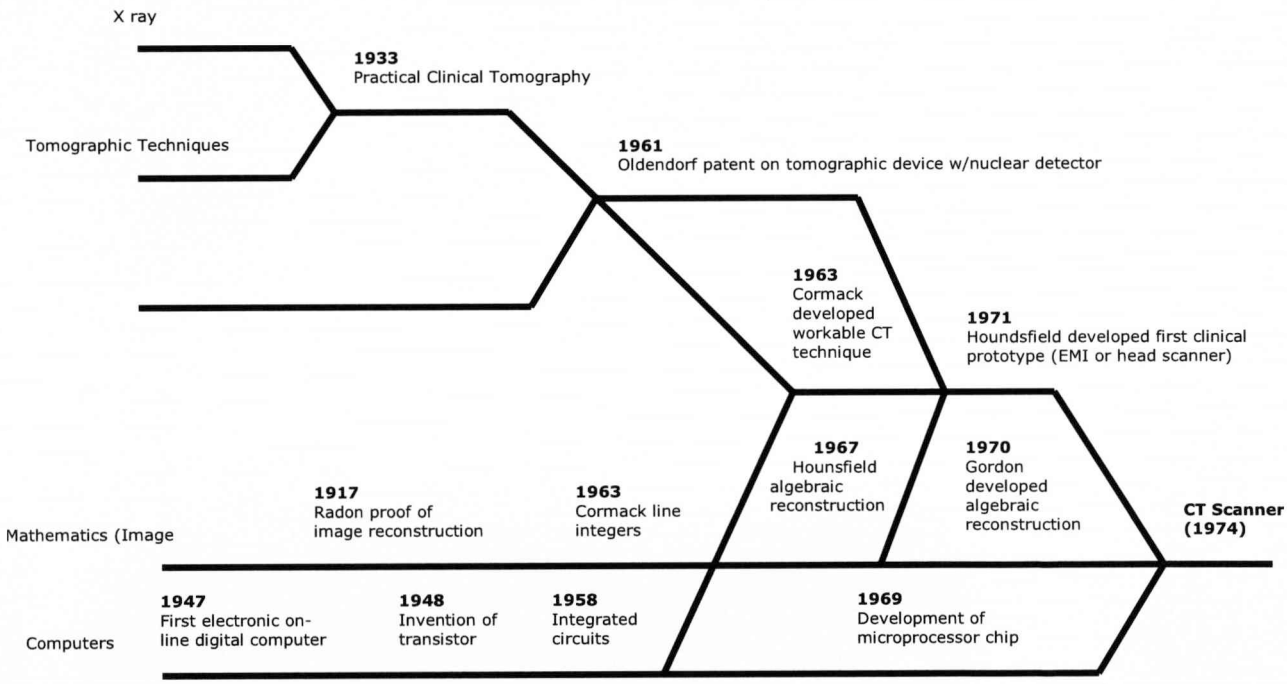
The period since World War II has seen the most rapid development of healthcare technology in history facilitated by an explosion of medical knowledge. The structure of DNA was discovered and new imaging devices emerged, like Computed Tomography (CT) scanners in 1972 and Magnetic Resonance Imaging (MRI) in 1975. The first commercial MRI scanner was produced in March 1980 while the first whole-body Positron-Emission Tomography (PET) scanner appeared in 1977, both of which radically changed the process of diagnosis. New therapeutic technologies such as laser and radiotherapy have improved the methods and effectiveness of therapeutics considerably. Production of biologic drugs and development of biotechnology in 20th century increased the availability and effectiveness of drug therapies considerably.

A new or improved technology develops through a process that flows from basic research to applied research and finally to targeted development (OTA 1976). Basic research is aimed at understanding the nature and principles of underlying processes. Applied research refers to research that is aimed at specifically manipulating or controlling a specific medical problem and is therefore primarily a goal-oriented activity. In reality, however, the process of new technology development is far less systematic and more complex and dynamic than this simple model indicates (Geljins and Their 1990). Improved health technology results from the combination of a wide range of interactions between many fields of sciences and technologies, for example physics, chemistry, electronics, biology, biochemistry and engineering, over a significant period of time.

A wide range of theories are proposed to explain the underlying process of technological innovation. Some theories stress the importance of identifying the right path to guide research while others emphasise the

importance of the specific characteristics of the inventor and the crucial role played by serendipity. However, each theory emphasises that uncertainty and variability are important characteristics of the process of technological change (Banta and Luce 1993). The development of CT scanners provides a useful case study to illustrate the process of the development of a new health technology. CT scanner is result of combination of X-ray equipment with a computer and a cathode ray tube to produce images of cross sections of human body (Battelle Memorial Institute 1973); (Battelle 1976). Figure 2.3 summarises the development process of CT scanners.

Figure 2.3 Development of the C.T. Scanner (Source Battelle 1976)



As healthcare technologies were increasingly becoming available, concerns were also growing about their safety, quality and effectiveness. Beeson compared recommended treatments in a 1927 textbook of medicine to those recommended in 1975. He rated 60% of the remedies in 1927 as harmful, dubious, or merely symptomatic with only 3% of recommended treatments being assessed as providing fully effective treatment or prevention. However, by 1975, the proportion of effective treatment

increased seven-fold and dubious ones decreased by two thirds (Beeson 1980).

The rapid changes in healthcare technologies raised a number of fundamental questions concerning the implications of health technology in many areas of society. How can we ensure safety? How can we evaluate effectiveness? Will the cost of new health technologies be affordable to society? A range of ethical issues became crucial to the adoption, dissemination and utilisation of new health technologies. Evidence-based medicine and health technology assessment were proposed as the appropriate techniques to generate some useful answers to these questions.

2.4 Evidence-based medicine and Application to HTA

2.4.1 Introduction

Evidence-based medicine (EBM), as a scientific approach to medical services, has a very long history (Claridge and Fabian 2005). One of the earliest recorded examples of EBM dates back to 1061, when Tu Jing wanted to evaluate the efficacy of ginseng to treat disease (Shang 1994); (Gong and Gluud 2004). He suggested that in order to evaluate the effect of genuine Shangdang ginseng, two persons were asked to run together. One was given the ginseng while the other ran without. After running for approximately three to five li (equivalent to 1500 to 2500 meters), the one without the ginseng developed severe shortness of breath, while the one who took the ginseng breathed evenly and smoothly. Challenges on the efficacy of bloodletting (Helmont 1662); (Clark 1678); (Louis 1836); (Milen and Chalmers 2002), debates on treatment of scurvy (Woodall 1639); (Lind 1753), and the development of a range of surgical techniques (Clark 1678); (Alanson 1782); (Tröhler 2003[a]); (Tröhler 2003[b]) are all historical examples of the use of EBM in developing medical science.

Claridge named the late nineteenth century the "transitional era of EBM" (Claridge and Fabian 2005). Ernest Amory Codman (1869-1940), with his simple but important concept of "the end result idea", is recognised as a pioneer of evidence-based medicine (Ernest and Codman 1990); (Kaska and Weinstein 1998). His practice was to record on a number of cards the details of all the preoperative and postoperative procedures for each operation. The cards were brought out a year later and the patients re-examined and evaluated for the results of the therapy. He developed a classification of adverse outcomes and reported the results widely to colleagues. His idea was to compare hospitals and surgeons in terms of the outcomes of a medical practice *before* and *after* a change in practice (Kaska and Weinstein 1998). The concepts underlying randomized control trials (RCTs) were also being developed at that time (Claridge and Fabian 2005). The clinical trials of streptomycin in pulmonary tuberculosis during the 1940s and the effects of calcium and vitamins A and D on the incidence of pregnancy toxaemia in 1937 were examples of two early RCTs (Theobald 1937); (Yoshioka 1998).

The modern concepts underlying EBM began during the late twentieth century (Claridge and Fabian 2005). EBM as a healthcare policy emerged in response to criticisms on the effectiveness of a wide range of medical treatments. Many of the most commonly used procedures or therapies had, at best, unproven effectiveness as they had not been adequately evaluated in the context of an RCT to assess their effectiveness. The growth of evidence-based medicine occurred against a background of health care reform, managed care, cost containment and quality improvement. Within this environment, clinicians have been urged to adopt the rigors of science while remaining true to their 'clinical judgment'. This tension - between efforts to make medical practice more scientific and the suspicions of many clinicians - has caused one of the greatest practical and ethical challenges in the history of the health professions (Claridge and Fabian 2005).

2.4.2 What is evidence-based medicine?

EBM focuses on the combination of individual clinical experience, utilising the best evidence available and effectively responding to patient values. It is a methodology for evaluating the validity of research in clinical medicine and applying the results to the care of individual patients. Evidence is gathered through a systematic literature review, and is critically appraised. The results are then integrated with physician/patient preferences to assist decision making. EBM facilitates the conscious, explicit and judicious application of current best evidence from clinical research combined with patient preferences and the physician's judgement to generate a powerful tool to help physicians deliver the right care at the right time in the right manner (Diamond 2000).

2.4.3 Why use evidence-based medicine?

EBM is playing an increasing role in clinical decision-making and enhancing its position in medical sciences and information. During the 20th century, many new pharmaceuticals became available for clinical use. While they all conformed to safety, quality and efficacy requirements, evidence of effectiveness in clinical practice was not necessary for them to gain market access (Taylor, Drummond et al. 2004). The development of EBM as a systematic approach for generating medical information synthesises the medical information about available health technologies and makes it possible to bring an enormous literature under control in order to inform clinical decision-making effectively.

A second role of EBM is in optimising resource use in healthcare services. This may be achieved, for example, by development of evidence-based clinical practice guidelines or through coverage decisions, for example in insurance based health systems (Claridge and Fabian 2005). Such guidelines provide clear information supporting more effective treatments and care as well as discouraging ineffective and poor quality medical services (Diamond 2000).

The increasing complexity of healthcare delivery systems necessitates the utilisation of EBM in healthcare management system (Grayson 1997). Health systems are expected to deliver their services to patients to the best available quality and on time. Evidence-based medicine (EBM) is a powerful tool for health- care organizations to demonstrate their commitment to quality care, ensuring they deliver the right care, to the right person, and at the right time (Diamond 2000).

2.4.4 EBM as a managerial tool

EBM is highly attractive for both politicians and managers in ensuring value for money in the use of public funds and promoting the dissemination of best practice by allocating available resources to therapeutic or diagnostic applications on the base of the best available evidence. However, the use of EBM as a tool to "save" money raises a number of issues. Firstly, EMB can be perceived as a method by which politicians or managers can deprive the population of health care (Grayson 1997). Secondly, clinical guidelines usually ignore cost-effectiveness which may result in the sub-optimal allocation of resources. Only by explicitly taking into account costs and embracing a broader conceptualisation of the value of health care outcomes, can EBM succeed in focussing healthcare on the most effective and efficient therapies (Sheldon 1997). Thirdly, the implementation of evidence-based healthcare raises a range of significant challenges to the traditional culture and practice of medicine (Grayson 1997).

To achieve wider acceptance, EBM must find the appropriate role for both research-based and experimental evidence and identify an explicit and scientific approach to combining them in practice with the individual views and preferences of clinicians. Research evidence is more likely to generate statements of benefit and costs which can be interpreted and used to support local decision-making (Grayson 1997).

2.5 Implementation Phases of EBM

Selecting measures, generating results and improving cares are the three phases of EBM to ensure its successful delivery (Diamond 2000). Each of these phases are examined in greater detail in the following sections.

2.5.1 Phase I - Selecting measures

This phase consists of three distinct stages. In the first stage, conditions that will benefit most from the application of EBM are identified. A good place to start is the most prevalent and costly diseases within the population and for which evidence shows significant variation in patterns of clinical practice which would appear to indicate clinical uncertainty.

The second step is to conduct literature searches to identify applicable practice guidelines. These guidelines provide a description or standard specifications for care of patients with specific diseases and have been developed through a formal, consensus-building process that incorporates the best scientific evidence of effectiveness together with scientifically derived expert opinion.

Assessing the validity of these guidelines and their "convert-ability" into performance measures is the third step in this phase. Not all guidelines can be readily converted to measures because of their complexity or the lack of accessible available data.

A common mistake in this phase is to underestimate the difficulty of choosing measures acceptable to all key stakeholders. Diamond believes that the solution is to involve physician leaders in the entire process, particularly in this first phase of the program (Diamond 2000).

2.5.2 Phase II - Generating the EBM Results

This phase, also, comprises three stages. The first stage is converting the selected guideline specifications into measures of performance. This is precise work that requires development of the "numerator" and

"denominator" populations that most closely match those described in the guideline. It requires codification of complex logic and includes time-specific application of recommended procedures.

The second stage is building an analytically ready database. To gather the necessary data sets for creating these measures it is necessary to emphasize the reliability and standardization of the data. These will ensure the generation of valid measures and proper configuration of the data. Starting with simple measures and moving along the scale to more complex measures is a good strategy to complete the data set. Data sources and data management issues also become more complex along the continuum.

The third stage is linking this database to the reporting application and starting generating results. An iterative approach is required to test and refine measures to ensure that final results are applicable and accurately reflect the underlying guideline. Without accuracy, EBM loses credibility and without applicability, the results provide interesting statistics without a roadmap for improvement.

2.5.3 Phase III - Improving Care

This phase includes two stages. Producing and distributing reports to physicians and other stakeholders represents the first stage. The reports should achieve four objectives:

1) Provide detailed information that can be acted upon by the physician
2) Provide graphic representation of this data
3) Document the methods used to compile the data
4) Provide relevant background information and literature references that support the practice guidelines from which the measures were developed.

The second stage is to implement programs designed to ensure the results are incorporated into day-to-day physician practice. Without these support efforts, EBM will fail to achieve success in improving care delivery. Table 2.2 summarises the process of EBM in practice.

Table 2.2 Process of evidence based medicine

Phase	Steps	Criteria
I. Selecting Measures	a. Selecting Topics b. Providing Guidelines c. Assessing Validity and Ability of Guidelines	• Most prevalent and costly • Applicability • Acceptable measures to all stakeholders
II. Generating Results	a. Selecting Guideline Specifications into performance measure b. Building Database c. Linking Database to The reporting Application	• Compatibility • Reliable & standard
III. Improving Care	a. Producing Report To stakeholders b. Implementing Programmes	• Informative & clear

It would appear that EBM emerged to establish whether a treatment or other intervention does more good than harm and is safe and effective. However, making choices comparing cost between available interventions has become one of the important concerns of healthcare decision-makers. The focus has switched from "does it work", to "is it cost effective?" As economics is all about choices based on value and costs, health economics emerged to help making choices in the health care setting easier. The development of this discipline is explored in greater detail in Section 2.6.

2.6 Historical development of health economics

The earliest healthcare economic evaluation referenced by health economics bibliographies is a study of the cost of tuberculosis published in 1920 (Lees 1961). However, Sorkin (1961) sets the earliest work as long ago as 1699 when Sir William Petty calculated "the rate of return obtained by moving the London population outside the city during epidemics of the plague" (Culyer 1971). Other early evaluative studies in the twentieth

century include some on the cost of mental illness, (Feldstein 1967) road accidents, alcoholism and various categories of disease (Culyer 1971). The first study on healthcare explicitly labelled 'cost–benefit' is one on water supply investments (Williams 1974), emphasising that the systematic economic evaluation of healthcare services does not have a long history.

The identification of resource scarceness for healthcare services started when the Institute of Economic Affairs published a paper entitled "Health through choice" (Lees 1961) Lees introduced a market discipline for the NHS and argued that medical care was not significantly different from the generality of goods that were supplied in the market. The debate continued through Arrow's article on "Uncertainty and the Welfare Economics of Medical Care" in the US and later in 1966 in the UK by Feldstein's book "Economic Analysis for Health Service Efficiency and Culyer's paper "the nature of the commodity 'health care' and its efficient allocation" (Feldstein 1967); (Culyer 1971). Maynard stated that the subtitle of Health Economics was introduced through the development of the Health Economics Study Group (HESG) in 1972. He stated that this subdiscipline "has matured and helped to create an international 'mafia' of friends and colleagues across the world" (Maynard and Donaldson 1998).

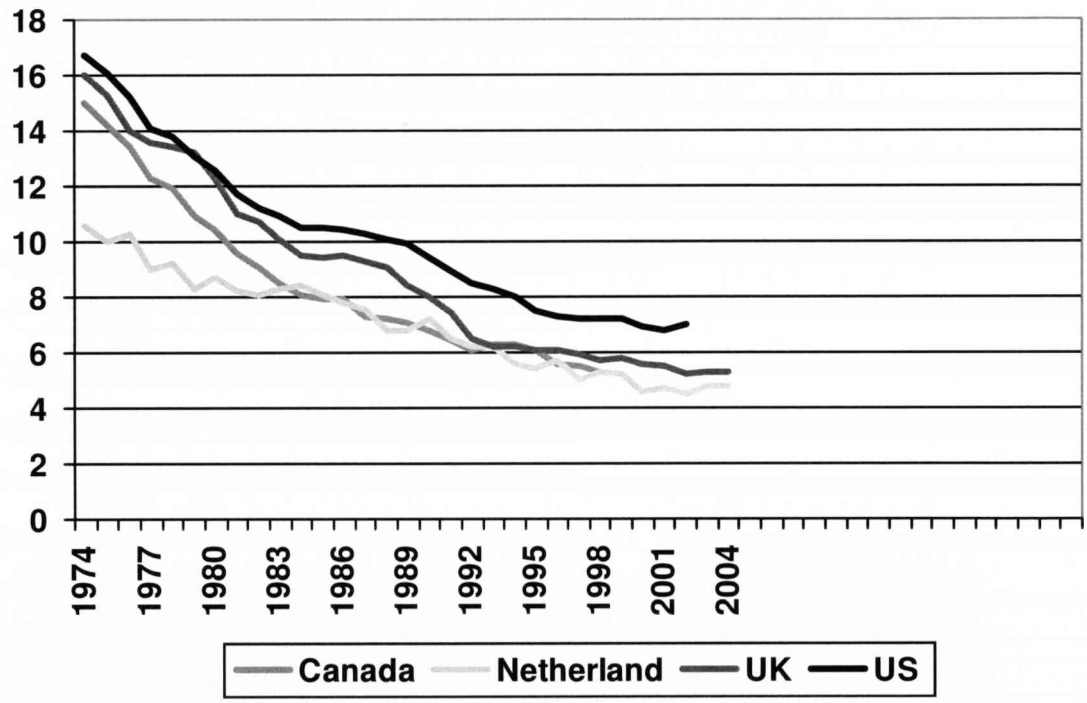
2.7 Concerns about healthcare technologies

2.7.1 Introduction

The experience of most countries emphasises that all age groups enjoy higher life expectancy today than at the turn of the century. The gains have been particularly remarkable for infants and children (Figure 2.4) and the role of new health technologies in achieving such health benefits has been crucial. The role of health technologies in this development has been important. Health technologies have affected society both by their beneficial effects on health status of the population and by their harmful effects of consuming resources that could be used elsewhere in the society. Thus it is important to assess if the health achievements are

worth the resources devoted to their achievement. Furthermore, it is essential to realise that an important part of reduction in mortality and morbidity of disease is attributable most directly to economic, societal, and environmental developments and not to new health technologies (Abel-Smith 1976). Higher income, better housing, better nutrition, safer work conditions, improved knowledge of health by public health programmes, and a wide range of other factors have also contributed (Gravelle, Wildman et al. 2000).

Figure 2.4 Reduction of infant mortality rate per 1000 live births in selected countries



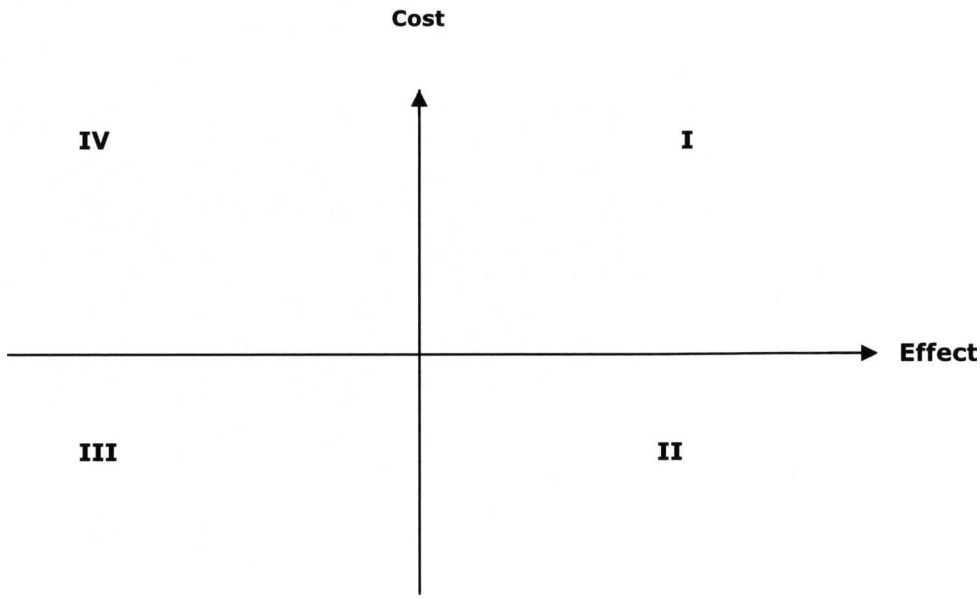
2.7.2 The impact of new technologies on health and healthcare costs

New health technologies have imposed significant beneficial effects on health status with the mortality reduction in the late nineteenth and twentieth century being largely attributable to scientific gains in the fields of bacteriology, chemistry, and biology. Improvements in the fundamental understanding of the aetiology of infections and communicable diseases made a broad range of health-improving interventions possible, including

the provision of sanitary water and food (Esrey, Potash et al. 1991). Development of various kinds of vaccines, like the polio vaccine, surgery, radiation, chemotherapy, and antibiotic treatment of infection disease prolonged both patients' life and increased their quality of lives considerably. However, such benefits are achieved at a cost and several studies have been undertaken to discover the main factors responsible for increasing the cost of healthcare services (Waldman 1972); (Altman and Blendon 1979); (Klarman 1979); (Mushkin 1979); (Banta, Behney et al. 1981[b]; (Congress 1984). What is clear from them is that new health technologies have caused increases in health care costs, but many other factors also contribute such as demographic changes, and enhanced patient expectations.

In a few cases, such as the advent of immunisation for communicable diseases, new technologies have both improved health and reduced health care costs (quadrant II in Figure 2.5). However, new technologies, most often, improve health and increase cost at the same time (quadrant I). In some cases new technologies reduce health and increase cost, as in the use of Clofibrate for the treatment of heart disease (quadrant IV). Finally a new health technology can decrease health and reduce cost (quadrant III), though such a technology is unlikely to be ethically acceptable. Figure 2.5 divides the potential impact of health technologies on health status and health expenditure into four distinct areas.

Figure 2.5 The Cost Effectiveness Plane (Black 1990)



The horizontal axis represents the difference between the benefits provided by alternative treatments. The vertical axis represents the difference between the cost of alternative treatments. Decisions for choices in quadrant II and IV are easy and clear. In quadrant II the new technology dominates the alternative while in quadrant IV the opposite is true.

Clearly healthcare managers and healthcare policy makers need to choose the best among available health technologies and use them efficiently in prevention, diagnosis, treatment, and palliation of diseases and other health problems. Most of health economics and economic evaluation is applied in the quadrants I and III to generate information regarding whether the effects of new technology are worth the cost.

2.8 Philosophy of Health Technology Assessment

The development of Health Technology Assessment (HTA) followed a pattern similar to that of Health Economics and Evidence-Based Medicine. That is, HTA, like EBM and health economics, emerged as the result of

technology revolution in the field of healthcare, increasing expectation from health services, growing demand for healthcare and, consequently increasing healthcare expenditure.

Many factors influenced the development of HTA and have made it an important part of the modern health system. Initial evaluations of therapeutic methods and medical devices revealed a range of faults in the past assessment of drugs and devices. One of the most classic examples of these health technologies is Gastric freezing. Gastric freezing developed in mid-1950s to treat peptic ulcer disease by circulating very cold alcohol through the stomach. The aim was to kill acid-producing cells. However, after using this technology extensively for a decade, clinical trials published in 1964 showed no benefit (Fineberg and Hiatt 1979). Diethylstilbestrol (DES) is another example. DES used for treatment of threatened abortion. It introduced in the late 1930s and though controlled studies in the 1950s showed no benefit from that treatment, DES was used as a treatment of pregnancy complications by 1970 (Apfel and Fisher 1984) and later proved to cause adenocarcinoma – OMA of female children of women who had used it.

Technological imperative, the lack of standardisation of critical evaluation, financial incentives, and the practice of "defensive medicine" combined to encourage the introduction of new healthcare technologies in a manner that imposed a huge resource burden in the 1980's. A primary function of health technology assessment is, therefore, to ensure that increased costs are justified by sufficiently improved health (Feeny, Guyatt et al. 1986). Given this definition, the philosophy of HTA appears very close to the philosophy of EBM. The aim of HTA is, therefore, to shift the centre of gravity of health care decision making from "poorly understood ways by expert" (Cochrane 1971), towards an explicit consideration and incorporation of clinical and cost effectiveness.

2.9 HTA as a scientific concept

2.9.1 Diffusion of new technologies

In order to evaluate the effects of any technology assessment programme, it is important to understand the diffusion process of a health technology in advance. The goal of technology assessment is to ensure that effective and efficient new technologies diffuse rapidly while ineffective and inefficient ones do not diffuse at all (Feeny, Guyatt et al. 1986). Past experience appears to indicate that many diffused rapidly, without a prior demonstration of their effectiveness.

2.9.2 Issues in the diffusion of health care technology

A number of conceptually distinct issues are often inter-linked in the literature on health technology and its diffusion. Discussion of health technology frequently considers five related issues: Innovation, technological development, evaluation, diffusion, and efficiency.

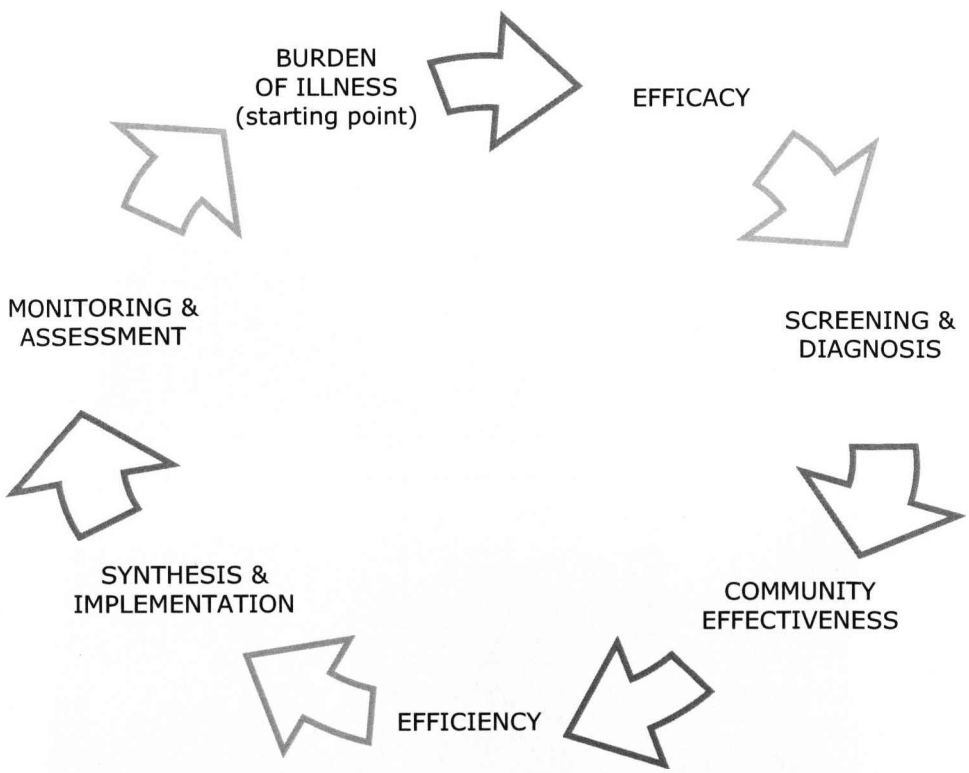
New technologies will be rapidly adopted if decision-makers perceive adoption to be in their interest. Organisational behaviour may be involved, but key adoption and utilization decisions are frequently made by or for physicians. Providers have multiple objectives in adopting new technologies, including financial considerations, prestige and professional competition, together with a commitment to improving patient care and maximising health benefits. From the commissioners' perspective, a different range of factors may affect the rate of adoption of new technologies. These include the perceived severity and urgency of the healthcare problems being addressed, the availability of therapeutic alternatives, the compatibility of new technology with the current style of practice, the prestige of the key opinion leaders supporting the new technology, patient preferences, physician attitudes, and the regulatory framework (Fineberg and Hiatt 1979).

2.9.3 A framework for the evaluation of technology

The Technology Assessment Iterative Loop (TAIL) was developed to provide a systematic approach to the health information necessary for rational decision making on the diffusion of health care technology. This framework subdivides the spectrum of health information into sub-groups that constitute a logical progression from quantifying the burden of disease, through use of technologies to diagnose the cause of disease, to validating intervention that prevents or ameliorates disease, to selecting the application and diffusion of these interventions, and coming full circle, to determining whether the burden of disease has been reduced.

The Loop format (Figure 2.6) emphasizes the importance of monitoring after implementing a health intervention to determine whether the planned reduction in the burden of illness is achieved.

Figure 2.6 The Technology Assessment Iterative Loop (Feeny, Guyatt et al. 1986)



Burden of illness, efficacy, screening diagnosis, community effectiveness, efficiency, synthesis and implementation, and monitoring and reassessment represent the seven steps in the technology assessment iterative loop (Tugwell, Bennett et al. 1985).

Goodman (Goodman 2004) however believes that there is significant variation in the scope, selection and level of detail in the methods of HTA. He and his colleagues have summarised ten basic steps involved in the HTA process:-

1. Identify assessment topics
2. Specify the assessment problem
3. Determine locus of assessment
4. Retrieve evidence
5. Collect new primary data
6. Apprise/interpret evidence
7. Integrate/synthesize evidence
8. Formulate findings and recommendations
9. Disseminate findings and recommendations
10. Monitor impact

The European Collaboration for Health Technology Assessment provides the following framework for HTA:-

1. Submission of an assessment request/identification of an assessment need
2. Prioritization
3. Commissioning
4. Conducting the assessment
    a. Definition of policy question
    b. Elaboration of HTA protocol
    c. Collecting background information/determination of the status of the technology
    d. Definition of the research questions

e. Source of data, appraisal of evidence, and synthesis of evidence for each of:
    i. Safety
    ii. Efficacy/effectiveness
    iii. Psychological, social, ethical
    iv. Organizational, professional
    v. Economic
f. Draft elaboration of discussion, conclusions, and recommendations
g. External review
h. Publishing of final HTA report and summary report

5. Dissemination
6. Use of HTA
7. Update of the HTA

This review of the range of processes of undertaking HTA emphasises the strong similarities between assessment programmes, however there are subtle differences. For example, although dissemination of findings and recommendations and monitoring of impact of the HTA are important aims of doing HTA, many assessment programmes may not include these parts in their HTA process (Goodman 2004).

2.10 HTA as a decision support mechanism

There are a number of general factors that need to be considered in attempting to implement an effective HTA programme. These are:-

1) How to select the topics for assessment
2) What kind of the methods to use for assessment
3) Where and who to report the results of the assessment
4) How to implement the results of the assessment

The development of the HTA has played an important role in healthcare policy and management (Banta and Vondeling 1994) and increased

managerial control on the utilization of healthcare resources (Drummond 2004). It has also raised a wide range of questions and challenges (Hill, Mitchell et al. 2000); (PausJenssen, Singer et al. 2003). As HTA consists of many components, such challenges cover a wide range of features of HTA. Many of the questions focussed on perceived imperfections in the methodologies applying to HTA. These perceived imperfections originate partly from imperfection of data and partly derive from the methods of data analysis. For example, it has been argued that EBM ignores the uncertainty inherent in much of medical practice, and arbitrarily excludes the valuable knowledge and understanding that can be provided by what have been called the "non-biological arts" (Smith and Taylor 1996). Hill and his colleagues, also, pointed out that in 326 pharmacoeconomic analyses submitted to the Pharmaceutical Benefit Advisory Committee in Australia between 1994 and 1997, there were a total of 249 identifiable methodological problems. Grayson critiqued the value-judgements underpinning the studies and stated that not all that is measurable is of value, and not all that is of value can be measured (Smith and Taylor 1996); (Grayson 1997); (Hill, Mitchell et al. 2000).

The second source of concerns related to the implementation of HTA results (Cookson and Maynard 2000). HTA programmes employ various methods in different countries (Carlsson, Jonsson et al. 2000); (Cranovsky, Schilling et al. 2000); (Fleurette and Banta 2000); (Lauslahti K, Roine et al. 2000); (Wild 2000); (Woolf and Henshall 2000); (Orvain, Xerri et al. 2004); (Stevens and Milne 2004) with such differences being attributed, mainly to variations between the health systems in each country (Banta and Vondeling 1994). What is important is that these variations in structure and institution have shaped a variety of methods by which HTA can influence decision-making and improve healthcare in each country.

The third set of the criticisms relate to the impact of HTA on various parts of health system as well as health related industries (Duthie, Trueman et al. 1999); (Hill, Mitchell et al. 2000); (Drummond 2004). Many studies have reviewed the variable impact of HTA on the different components of

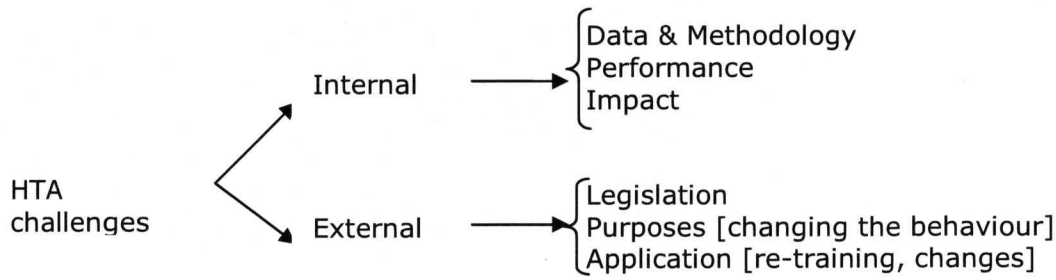
the health systems (Banta and Perry 1997); (Rutten 2004) and confirm that HTA programmes have made a considerable contribution to health policy and healthcare management (Berg, Van der Grinten et al. 2004); (Carlsson 2004); (Douw and Vondeling 2006), but some have questioned the extent of the positive impact of HTA on health systems (Drummond 2004).

Finally, the degree of acceptance of the HTA by health professionals and society in general is another important challenge (Grayson 1997). It is important to note that while some health care professionals are convinced about the value of HTA, others believe that the application of HTA in practice raises many unforeseen problems. For example, HTA evaluation may identify new technology as being clinically and cost effective, but it may be difficult to implement in practice because it requires retraining, changes in working practices or other managerial changes. Decision-makers may also be reluctant to implement the result of a HTA study until they have proved its value for themselves. The third difficulty in implementing HTA results is the inherent difficulty in changing the attitudes and behaviour that underpin a change in clinical practice. The fourth concern in acceptance of the HTA programme is worries about the final result of the application of HTA. In essence, it is feared that HTA may simply become used for rationing based on economic rather than clinical criteria (Grayson 1997). Finally, the specific characteristics of the medical professionals make the acceptance of HTA more difficult. Strong professional values, high social status and, occasionally, resistance to external interference are notable characteristics of the medical profession. Health professionals may perceive that their professional competence is being questioned and their clinical freedom threatened by people who are frequently no longer in regular contact with patients (Tanenbaum 1993); (Rafuse 1994).

The current challenges facing HTA programmes may be classified in two main groups (internal and external challenges). The internal challenges might be integrated to three factors; data and methodology, process, and distribution. The external challenges could be sub-headed to legislation,

purpose, and application. Figure 2.7 summarises the challenges facing HTA programmes.

Figure 2.7 Summary of HTA Challenges



2.11 Types of HTA Policy and Organisation

From a policy perspective, two general types of HTA systems currently exist in various countries. The first type of HTA generates information and knowledge on an advisory basis, with the hope that such information will be used by health workers to improve efficiency and quality of health services. One of the good examples of such system is the HTA system in the USA (Eisenberg and Zarin 2002). The second type of HTA system is more directive and enforces their decisions on healthcare systems. A good example of this type of HTA system is that currently utilised in the UK.

2.12 Discussion and overview

New technologies have changed the face of the world and significantly influenced every human activity. They have also improved many aspects of the social activities and living standards of populations. However, new technologies also have imposed adverse social, political, and economic side effects (OTA 1976). Global warming, air and water pollution, nuclear weapons, chemical and biological weapons, car and airplane crashes are common and important concerns. Technology assessment has been evaluate the desirable, undesirable, and uncertain consequences of new

technologies and is essential to ensure that the benefits of technology utilizations outweigh any adverse effects.

The adoption of new health technologies has led to significant improvements in the health status of populations by reducing mortality and increasing life expectancy (W.H.O. 2005). However, the new technologies have also raised health expenditures considerably which could decrease affordability of healthcare and consequently decrease the availability of care for poorer parts of society. High cost health technologies can also 'crowd out' investments in other parts of the healthcare services.

Health technologies differ from other technologies in a number of respects. Firstly, health technologies impose a direct impact on individuals; and therefore their desirable or undesirable effects would appear sooner than with many other technologies. Secondly, health technologies usually are utilised by highly trained professionals, and individuals can use them only via the involvement of a medical worker. The consumers of heath technologies normally have very little information or expertise concerning the technology. The third difference between heath technologies and others is the method of payment for health technologies. That is, health insurance organizations or governments usually purchase the health technologies. In most countries, governments have a major responsibility for the quality, quantity and availability of healthcare services.

As the nature of healthcare technologies differ from other technologies, equally healthcare technology assessment also differs from technology assessment. The first difference is that the main targets of the HTA results are health managers and health professionals which has important implications on how the report of a HTA should be prepared. The second difference is that while TA developed mainly because of socioeconomic and environmental adverse effects of new technologies, HTA developed largely due to scarcity of healthcare resources. The main philosophy underlying the development of the TA related to protection of the human

society and the environment. However, the philosophy of HTA development has been to improve healthcare decision makers to increase quality of healthcare as well as efficiency and equity.

HTA, however, may be considered as a new technology itself. As there are concerns about distribution of new health technology before evaluation (Banta, Behney et al. 1981[b]; (Feeny, Guyatt et al. 1986), it is necessary to consider the cost and benefit of HTA before its application, Although the information for previous evaluation were not available for current HTA programmes, there are valuable information, experiences and lessons being generated by existing HTA programmes that could be used to develop and transfer HTA to new countries with different health systems and various levels of resources. It is with this in mind that the remainder of this thesis is written.

CHAPTER 3

METHODOLOGY

3 METHODOLOGY

3.1 Overview of methodology

The structure of the health care system in Iran is grounded in its economy and demography, as well as its management and politics. A good healthcare evaluation plan, therefore, must encompass all factors that will significantly affect healthcare. These include the nature of the programme, the interests of the stakeholders, political and economic situations, and demographic changes and trends (Rossi, Freeman et al. 1999). The structure, process and outcomes of healthcare can be studied at the macro or micro level of analysis. The macro level refers to the population perspective on the determinants of the health of communities as a whole. The micro level analyses factors that contribute to the health of individual patients. HTA, as a policy or programme, could be categorised as a macro policy and evaluations should therefore be undertaken at the macro level.

The first step in designing a HTA programme is to perform a Needs Assessment (NA) for the programme to understand to what extent HTA could help the health system in improving its effectiveness, efficiency and equity (EEE). The first step in NA is exploration of the gap between the current status and where they should be (Stout 1995) which requires a detailed analysis of the current status of the health system. The 'status' of the Iranian health system is examined in relation to its performance in relation to the objectives of achieving effectiveness, efficiency and equity in healthcare delivery. To evaluate current status, several medical databases and local Iranian journals, books, theses and publications were searched to ensure that all published materials are incorporated into this study. The results were limited, difficult to access and left many questions unanswered. The aim of the literature search was to collate and analyse in as comprehensive a manner as possible all available evidence concerning the current performance of the Iranian healthcare system.

In response to the limitations in academic and governmental published materials, numbers of individuals were chosen to participate in interviews and discussions as it became evident that multiple strategies of data collection were required to provide greater validity for our analysis. In particular, qualitative methods of data collection were required, gathering available governmental publications and data, searching academic publications and local news agencies to ensure the comprehensive collection of information required to undertake the analysis.

The majority of evidence underpinning this analysis has been obtained from interviews and aimed at sharing the understanding and experiences of policy makers and health providers concerning the challenges facing the Iranian health system and the influences on the Iranian healthcare system.

Recognition of the importance of analyses in health services research is growing (Mays and Pope 1995[a]; (Mays and Pope 1995[b]; (Green and Britten 1998); (Pope, Ziebland et al. 2000); (Snape and Spencer 2003); (Silverman 2005). Given the complexity, uncertainty and the comparative paucity of published materials about the Iranian health system, a qualitative approach was identified as being the most appropriate research method for the following reasons:-

Firstly, qualitative analysis allows researchers to address systematically research questions that are not easily analysed using conventional quantitative methods (Snape and Spencer 2003); (Silverman 2005). The underlying epistemology is based on an understanding that there are different realities and ways of knowing. Qualitative methods are concerned with understanding the meanings that people attach to phenomena within their social worlds and is able to capture individuals' attitudes, beliefs, decisions and values in terms of the meanings individuals attach to them (Bryman 1988); (Denzin and Lincoln 2000). It is therefore suited to the study of decision-making processes and analyses how outcomes are achieved through the procedures involved, It can also

provide a greater understanding of how different perspectives give rise to the same challenge and problems of the system.

Secondly, a related advantage of qualitative analysis concerns the application of the inductive approach to theory development by which analytical categories can be identified as they emerge from the data. In this manner, theory is derived upwards from the data (Strauss and Corbin 1998) and provides effective methods of accessing unanticipated and complicated explanations arising from the health system in Iran.

Thirdly, qualitative research emphasises the context and the ways in which features of a specific situation or setting impact upon the phenomenon under study. Such an approach is entirely suited to the present study because it seeks to understand the process and the philosophy of decision-making within the field of health systems.

However, although qualitative analysis can provide valid and comprehensive information, it also requires direct contact with all interviewees and thus is time consuming and costly. The difficulties of this method are accentuated when "key informants" are amongst high ranked managers and politicians (Soriano 1995); (Rossi, Lipsey et al. 2004). Interviews with key informants are essential when we need to generate information in an environment where published information is lacking. In such circumstances, it is necessary to assess what managers of the health services think about their problems and current challenges (Rossi, Freeman et al. 1999).

Among the advantages of this method are the ability of participants to competently address specific topics and the limited number of participants needed, because key informants are presumed to have a broad knowledge of their targeted area (Soriano 1995); (Rossi, Lipsey et al. 2004). Further details of the method of sampling, conducting interviews and analysis of interviews are provided later in this chapter.

With the objective of increasing validity and reliability of the study, other available sources of relevant data, were also analysed including the publicised views about the health system and the direction of future healthcare policy of healthcare managers, health policy makers and politicians. These views were obtained from Iranian news agencies and newspapers. To collect all relevant opinions, all of the main Iranian news agencies and most national newspapers in Iran were analysed for the purposes of this study.

The third data source underpinning this study were official published materials relating to Iranian health care, national development plans, official websites of the Ministry of Health and relevant departments and the Iranian parliament's website. The range of data sources reviewed included the Iranian Statistical Centre database, Iran Pharmaceutical Statistical Letter, World Health Organisation database, and Economic and Social Data Services of the World Bank are used to collect reliable social, economical and health data, W.H.O. online database, World Development Indicators, and other relevant websites.

A detailed literature search was undertaken in two areas. First, a search was undertaken to identify relevant literature on HTA, its history, philosophy, application, system and current challenges. This search was initially undertaken in spring 2003 and updated in 2006. The search terms utilised were:

1. Health Technology assessment
2. Economic Evaluation
3. Health system
4. Healthcare Delivery
5. Health Care Delivery
6. Healthcare Financing
7. Health Care Financing
8. Equity
9. Efficiency
10. Effectiveness

11. Health Insurance
12. Pharmaceutical*
13. Pharmaceutical Industry
14. Pharmaceutical Factor*
15. Pharmaceutical Regulation

The results of this search were analysed for relevance and, where appropriate, obtained to inform the analysis.

Secondly, a search was undertaken to identify relevant documents, reports and papers relating to the Iranian health system. A comprehensive search was carried out of both English and Farsi databases as well as official websites of the Iranian Ministry of Health.

For English databases the search terms were:

1. Health System
2. Healthcare Delivery System
3. Health Care Delivery System
4. Healthcare Financing
5. Health Care Financing
6. Health Network*
7. Health Insurance
8. Pharmaceutical*
9. Pharmaceutical Industry
10. Pharmaceutical Factor*
11. Pharmaceutical Regulation
12. Iran
13. Iranian

For Farsi databases the same Farsi terms were used to find the relevant literature:

1. Nezaam-e Salaamat (Health system)
2. Nezaam-e Eraye-ye Khadamaat-e Darmaani (Healthcare Delivery System)
3. Tamin-e Maali-ye Khadamaat-e darmaani (Healthcare Financing)
4. Shabakehaaye behdaasht (Health Networks)
5. Bimehaaye Darmaani (Health Insurance)
6. Daarou-yee(Pharmaceutical)
7. Sanaaye-e Darouye (Pharmaceutical Industry)
8. Ghavaanin-e Darou-ee (Pharmaceutical Regulation)
9. Iran

This multi-faceted method of data collection ensured that a wide range of views and perceptions were incorporated into the analysis to ensure a 'realistic approach' (Silverman 2005).

3.2 Sampling procedure

Purposive sampling was employed as a rationale for selecting key informants. This is a deliberate, non-random method of sampling, which aims to select groups, settings or individuals in whom awareness of the processes being studied is most likely to be high (Denzin and Lincoln 2003). Purposive sampling also ensured that individuals and practices with a range of characteristics were analysed. The interviewees were selected from various parts of the health system to ensure that the sample was representative and encompassed a wide range of views. Interviewees were selected from a range of stakeholders including health authorities, health insurance organisations, pharmaceutical industries and politicians. In deciding on the nature and structure of interviews required, a logical sequence was followed. Firstly, a matrix of the desired characteristics of interviewees was developed to ensure that all important aspects of the information required was covered. Secondly, informants were identified to ensure comprehensive coverage of the information to be generated. Thirdly, consent was sought from desired interviewees with those not willing to participate being replaced by willing informants with similar

background and experience. Finally, semi-structured interviews were undertaken to ensure the collection of all necessary data while simultaneously providing the opportunity for informants to cover issues felt to be important but outside the initial interview framework.

The interviewees included the Deputy Minister of Health, Deputy Minister of Food & Drugs, the Head of the Social Security Insurance Organisation, the Head of the Medical Services Insurance Organisation and the Head of the Imam Khomeini Insurance Organisation. A total of forty senior policy-makers from various sections of the Iranian health system and twenty health professionals working with various health departments were selected for interview, but ultimately a total of 38 interviews were conducted lasting between 20 and 90 minutes. It is acknowledged that the number of interviews undertaken is largely 'opportunistic'. It represents a balance of the need to obtain as comprehensive an information set as possible with the time constraints that inevitably operate on any research strucrure. Denzin and Lincoln state that it is difficult to undertake a 'power calculation' to determine exactly the number of interviews required for a study (Denzin and Lincoln 2003), however, our aim was to maximise the number of interviewees to as many subjects as possible to maximise the breadth of responses (Kvale 1996). In addition to these interviews, the opinions of policy-makers and politicians were collected, considered and analysed from published materials (Table 3.5).

Although it is not possible to claim that we have collected all relevant information in this field, given the frequent agreement obtained in the interviews it is my belief that I have collected sufficient information to enable a comprehensive analysis of the potential role of HTA in helping to achieve the objectives of the healthcare system in Iran.

3.3 The interview process

All interviewees were offered the potential for confidentiality and if they preferred confidentiality they were assured that no information identifying

them would be used in any published material. Likewise, the subjects were asked if they were happy with the interview being recorded. Although many of them were not worried about publicizing their name, the decision was taken to keep all responders anonymous, but in order to emphasise the relevance of the information provided within the interviews, the position of the interviewees is presented in Table 3.2 to Table 3.4.

A semi-structured open-ended interview was utilised to provide a wider range of data, to enable respondents to partly determine the direction of the interview (Denzin and Lincoln 2003) and to "generate data which give an authentic insight into people's experiences" (Silverman 2000).

The main advantage of incorporating open-ended questions into an interview relates to the ability of the respondent to cover areas that perhaps had not been originally considered by the interviewer which ensures that a semi-structured interview is more flexible than a questionnaire or survey as it allows interviewees flexibility to talk about their experiences and views in their own words. In this manner, the interview process can gain understanding from the perspective of the individual, taking into account cognitive, affective and behavioural elements (Chell 1998). The semi-structure interview therefore provides a rich and detailed set of data by allowing respondents to determine which factors are most relevant to them for the event being investigated. It was chosen for use in the present context because it provides an opportunity to obtain an in-depth account of each respondents views.

The disadvantages of this method largely relate to the greater amount of time required to derive and transcribe the given materials, together with the risk that responses will not be easy to interpret (Soriano 1995). Furthermore, there is also the possibility that responses may relate to what the interviewer perceives should be related rather than a reflection of reality (Denzin and Lincoln 2003). Although acknowledging these potential weaknesses, the structure of analysis undertaken was held to be

the most appropriate method of obtaining information in a research naive environment.

Each interview had three phases. In the first phase, introductory information about the project and HTA was provided to the interviewees, together with its potential impact on the managerial field of the interviewee. All informants were very keen to get more information about the HTA programme.

The second phase of the interview addressed issues relating to the interviewees' field of work. It explored issues including the current challenges and future perspective of their departments. The aim of this phase was to identify the interviewees' opinions about the current challenges, problems and factors that were being faced in their fields of work.

The third phase of the interviews allowed the interviewee the freedom to express their perceptions on associated areas of interest.

The interviews were conducted between summer 2003 and autumn 2005. The interviewees were initially contacted by phone to explain the purpose of the interview and to obtain their agreement for the face to face interview. Three interviewees preferred to not record the interviews, the rest of the interviews were tape recorded. The issues addressed in the interviews are outlined in Table 3.1.

3.4 Data analysis

Data analysis is the process of interpreting the data obtained in the raw interviews to generate evidence on the issues of interest. The first step in this process is preparing the transcriptions in order to extract information on the concepts and the themes being addressed. A wide range of concepts, themes and events which described and explained the challenges of the health system and its potential solutions were

addressed. A concept is a word or term that represents an idea important to the research problem; Themes are summary statements and explanations of what is going on; and events are occurrences which have taken place (Rubin and Rubin 2005). The themes were classified and coded. Coding is systematically labelling concepts, themes, and events which enable researchers to readily retrieve and examine all of the data relating to the same subject across all of the interviews. After the coding, the interviews were systematically examined to clarify the concepts and themes and synthesize different versions of the events to synthesise an understanding of the overall challenges and difficulties facing the Iranian health system. Weighing and comparing the parallel themes were the next important stages in the analysis in order to elaborate new themes and concepts. The extractions of the meaning and implications of the interviews then were extracted from the interviews to reveal the "Facts" or "Events" that could provide the answers to the research questions. The final stage of the analysis was combining the concepts, themes and events to construct a description and analysis concerning how and why the Iranian health system has faced its current problems and to evaluate whether and to what extent a HTA programme could assist in confronting such problems. This thematic method of analysis (Denzin and Lincoln 2003); (Rubin and Rubin 2005), is used to analyse the interviews.

Table 3.1 The evaluation questions for the Iranian health system in various sections

Health Section	Evaluation Questions

Healthcare System	• How healthcare system is financing?
	  ○ Is there any challenge with this system?
	  ○ What is/are the cause/s of these difficulties?
	  ○ What is/are the solutions/s?
	• How do healthcare services distribute?
	  ○ Is there any challenge with this method?
	  ○ What is/are the cause/s of the difficulties?
	  ○ What is/are the solution/s?
	• How do you manage new and high cost technologies?
	  ○ Is there any challenge with this system?
	  ○ What is/are the cause/s of the difficulties?
	  ○ What is/are the solution/s?
	• Do you believe that HTA can help to solve any of these problems?

Health Insurance	• How do you cover new health technologies?
	• How and who does determine the policy premiums?
	  ○ Is there any challenge with this method?
	  ○ What is/are the cause/s of the difficulties?
	  ○ What is/are the solution/s?
	• How do you add or delete a care or a service to your policy?
	  ○ Is there any challenge with this method?
	  ○ What is/are the cause/s of the difficulties?
	  ○ What is/are the solution/s?
	• How do you manage new and high cost technologies?
	• Do you believe that HTA can help to solve any of these problems?

Pharmaceuticals	• How and who regulate pharmaceuticals in Iran?
	  ○ Is there any challenge with this system?
	  ○ What is/are the cause/s of the difficulties?
	  ○ What is/are the solution/s?
	• What is/are your main goal/s?
	• How and who does add or delete new drug to national drug list of Iran?
	  ○ Is there any challenge with this method?
	  ○ What is/are the cause/s of these difficulties?
	  ○ What is/are the solution/s?
	• How do you pricing pharmaceuticals?
	  ○ Is there any challenge with this method?
	  ○ What is/are the cause/s of the difficulties?
	  ○ What is/are the solution/s?
	• What is/ are the main problem/s of the current state?
	• Do you believe that HTA can help to solve any of these problems?

Table 3.2 Healthcare system interviewees and their roles

No.	Healthcare System	
	Name	Position
1	Dr. 1	Academic, Senior Policy Maker of the Iranian Health System (Summer 2003)
2	Dr. 2	GP, Director of Regional Health Network (2005)
3	Dr. 3	Vice Chancellor of Medical University
4	Dr. 4	Chancellor, Medical University (2003)
5	Dr. 5	GP, Director of Regional Health Network (2005)
6	Dr. 6	Health Scientist, Academic staff
7	Dr. 7	Cardiologist, Academic Staff
8	Dr. 8	Specialist, Director of Hospital
9	Dr. 9	Health Scientist, Deputy Chancellor of Medical University

Table 3.3 Health insurance interviewees and their roles

No.	Health Insurance	
	Name	Position
1	Dr. 10	Senior staff, Medical Services Insurance Organisation (2005)
2	Dr. 11	Deputy of Provincial Department of Imam Khmeini Health Insurance Organisation (2005)
3	Dr. 12	Senior staff, Imam Khmeini Health Insurance Organisation (2005)
4	Dr. 13	General Director of Insurance and Income at Medical Services Insurance Organisation
5	Dr. 14	Deputy of Medical Services Insurance Organisation (2003)
6	Dr. 15	Member of the Managing Board in Medical Services Insurance Organisation
7	Dr. 16	Executive manager of provincial department of Medical Services Insurance Organisation
8	Dr. 17	Director of Provincial Department Medical Services Insurance Organisation
9	Dr. 18	Senior staff in Social Security Health Insurance Organisation (Summer 2005)
10	Dr. 19	Senior Manager in Social Security Health Insurance Organisation (Summer 2005)
11	Dr. 20	Member of management committee of Medical Services Insurance Organisation (Summer 2005)

Table 3.4 Pharmaceutical interviewees and their roles

No.	Pharmaceuticals	
	Name	Position
1	Dr 21	Academic, Senior Staff, Food and Drug Department (Summer 2003)
2	Dr. 22	Managing Director of a Pharmaceutical Company
3	Dr. 23	Managing Director of a Pharmaceutical Company
4	Dr. 24	Pharmacist, Senior Staff, Food and Drug Department (2003)
5	Dr. 25	Pharmacist, Senior Staff, Food and Drug Department (2003)
6	Dr. 26	Pharmacist, Senior Staff, Food and Drug Department (2003)
7	Dr. 27	Deputy Chancellor of a Medical University in Food and Drug, (2003)
8	Dr. 28	Deputy Chancellor of a Medical University in Food and Drug, (2005)
9	Dr. 29	Pharmacist, Iranian Pharmacists Society
10	Dr. 30	Pharmacologist, Academic Staff (2003)
11	Dr. 31	Clinical Pharmacologist, Academic Staff
12	Dr. 32	Pharmacist, Staff, Food and Drug Department (2003)
13	Dr. 33	Pharmacist, Staff, Food and Drug Department (2003)
14	Dr. 34	Pharmacist, Staff, Food and Drug Department (2003)
15	Dr.35	Pharmacologist, Academic Staff, Ex-Deputy Chancellor of a Medical University (2003)

Table 3.5 High ranked health policy-makers and their roles*

No.	High Ranked Health Policy Makers	
	Name	Position
1	Dr Iraj Fazel	Ex-Minister of Culture and Higher Education
2	Dr Alireza Marandi	Ex-Minister of Health
3	Dr Malek Afzali	Ex-minister of Health
4	Dr M. Pezeshkiyan	Ex-Minister of Health
5	Dr M. B. Lankarani	Minister of Health (2004-continue)
6	Dr H. Toufighi	Ex-Minister of Science and Technology
7	Dr M.R. Zafarghandi	Ex-chancellor of Tehran Medical University
8	Dr Omidvar Rezaei	Member of Parliament
9	Dr M. Shahbaz Khani	Member of Parliament
10	Dr M. B. Sadr	Director of Iranian Medical Society

*All participants consented to be identified by name

CHAPTER 4

IRAN AND ITS HEALTH SYSTEM

4 IRAN AND ITS HEALTH SYSTEM

4.1 Introduction

This chapter analyses the Iranian healthcare system and evaluates its performance with respect to effectiveness, efficiency and equity. Many of the issues and challenges facing the health system are directly related to the strength of the economy and the characteristics of the Iranian population. For this reason, this chapter starts with an overview of the demography and economy of Iran and then analyses the health system based on documentary analysis. It then goes on to incorporate interviews with key decision-makers to elucidate many areas not well explained in the document. The methods for this documentary review and the interviews have been explained in Chapter 3.

4.2 Political and demographic background

Iran is officially the Islamic Republic of Iran (Jomhouri-ye Eslami-ye Iran), situated in the South West of Asia, in the Middle-East, and covers 1,648,000 square kilometres. Eastern Iran is dominated by a high plateau, with large salt flats and vast sand deserts. The plateau is surrounded by even higher mountains, including the Zagros to the West and the Elburz to the North. The Zagros Mountains extend from the North-West to South-East and the Elbourz Mountains span the North-West to North-East of Iran. The country shares borders with Armenia (35 km), Azerbaijan (432 km) and Turkmenistan (992 km) in the North, Afghanistan (936 km) and Pakistan (909 km) in the East, the Persian Golf and the Golf of Oman (2,440 km) in the South, Iraq (1,458 km) and Turkey (499 km) in the West (Source: National Geographical Society, 2001, Figure 4.1). Iran had 70,495,782 inhabitants in 2007 ((WHO) 2007); (I.S.C. 2007).

Figure 4.1 Geographical map of Iran and its neighbours

Source: National Geographic Society, 2001

The revolution of 1979 saw the overthrow of monarchy and the last Shah of Iran, Mohammad Reza Pahlavi, was forced into exile. Iran became an Islamic republic on 31st March 1979, when the Iranian population appointed their government by general election. The country consists of 30 provinces, 316 cities, 939 towns and 2353 villages (Table 4.1). According to their population size, provinces, cities, towns and villages have their own representatives in the parliament (majles-e shoraye eslami), where the main legislative authority of the country is located. Amendment of current laws, plans and programmes may be suggested by the cabinet or by some members of the parliament. Based on the Iranian political system, all laws, acts, regulations, and programmes must be ratified in the parliament before proceeding to execution. All members of the parliament are elected directly by the population for four years. Like members of the parliament, the president of the Islamic Republic of Iran is elected directly by all the Iranian population, who meet the minimum age criteria, for a period of four years. The president chooses the ministers and proposes them to the parliament for approval or dismissal.

The economy and the population of Iran have had considerable changes and challenges in the past thirty years. The economy faced radical internal and external shocks resulting in the GDP of the country decreasing sharply in the late 1970s and early 1980s (Figure 4.2). The population growth in Iran experienced its highest rate during the same period with the population doubling in nearly two decades (Table 4.2). This rapid rate of population growth highlighted the problems arising from the economic challenges faced in the past decades.

Table 4.1 Iranian Provinces and their cities, sections, towns and villages

Number	Name of the province	No. of cities	No. of sections	No. of towns	No. of villages	Population
4	Azarbayijan (East)	19	42	55	141	3603456
1	Ardebil	9	25	20	66	1228155
28	Azarbayejan (West)	14	36	34	109	2873459
2	Boushehr	9	21	25	42	886267
3	Chaharmahal & Bakhtiyari	6	17	26	39	857910
5	Fars	22	69	69	190	4336878
6	Ghazvin	4	18	20	44	1142656
7	Gilan	16	43	48	109	2403716
8	Golestan	11	21	23	50	1616317
9	Hamedan	8	22	24	70	1702456
10	Hormozgan	9	23	18	69	1403006
11	Ilam	7	18	17	38	545787
12	Isfahan	21		90	123	4559256
13	Kerman	13	39	50	141	2651150
14	Kermanshah	12	27	26	83	1878490
15	Khorasan (Razavi)	20	64	69	161	5593079
22	Khorasan (North)	6	16	15	41	811572
26	Khorasan (South)	6	16	17	42	636420
16	Khouzestan	18	40	44	118	4274979
17	Kohkiloiye & Boyerahmad	4	14	13	40	633997
18	Kurdestan	9	26	23	83	1439470
19	Lorestan	9	26	22	83	1715710
20	Markazi	10	18	27	61	1350614
21	Mazandaran	15	43	46	110	2921041
23	Qum	1	5	5	9	1046239
24	Semnan	4	12	16	28	589742
25	Sistan & Balouchestan	8	36	31	98	2405742
27	Tehran	13	34	44	77	13422366
29	Yazd	10	20	21	51	990346
30	Zanjan	7	16	16	46	964601
Total		320	807	944	2362	70495782

Data Source: Iran's Statistical Centre, 2007

An overview of the economy of Iran is required to understand its health systems more clearly because there is a direct link between private and public health expenditures and available resources (Haines 2003); (Hogberg 2005) and many of the healthcare challenges faced in Iran originate from its economic situation (Chapter 4). The economic wellbeing of Iranians impacts on their ability and willingness to pay for health care services (Lanjouw, Ravallion et al. 1996); (Bloom and Canning 2000) and many health policies respond to the economic challenges facing the population to help them obtain basic healthcare services. This chapter provides an analysis of Iran's economy and population during the last thirty years.

4.3 The Iranian economy

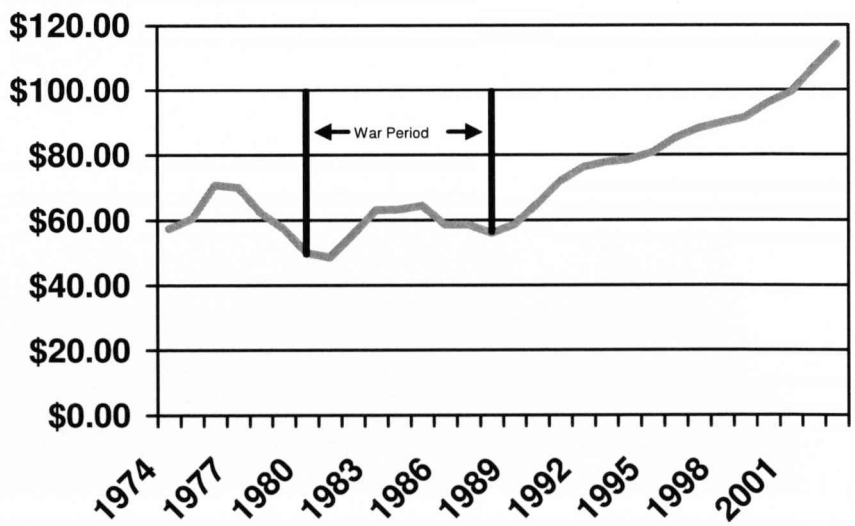
Iran's economy is based on three sections; state, cooperative and private. The state sector includes all large-scale industries such as foreign trade, large mineral resources, banking, insurance, energy, dams, radio and television, post, telegraph and telephone, aviation, shipping, roads, and railroad. As one of the main oil producers in the world, a substantial proportion of revenue received by the state comes from the sale of oil. Agriculture and industries are the second and the third sources of Iranian GDP respectively (M&PO 2006); (S.C.I 2006).

The performance of the Iranian economy has faced noticeable fluctuations in the past thirty years. These variations are partly attributable to the nature of the highly centralised economy of Iran prior to the 1979 revolution (Alizadeh 2000), partly attributable to the external shocks faced by the Iranian economy and partly attributable to economic mismanagement and lack of policy coordination (Hakimian and Karshenas 1999). The 1979 revolution, the eight-year war against Iran (1980-1988), a sharp reduction in oil revenue, and the freezing of Iranian foreign assets (as a result of an economic embargo against Iran) were amongst some of the external shocks imposed on the Iranian economy between 1979 and 1989. Such external shocks were combined with unstable

macroeconomic policies and a rapidly expanding population to produce pressures on the economy of Iran (Mazarei 1996); (Alizadeh 2000); (Pesaran 2000). The revolution, the Iraqi war against Iran, and the unfavourable conditions in the international petroleum market contributed to both a drastic decline and an increased volatility in oil revenues (Mazarei 1996).

The Iraqi war against Iran also imposed a heavy burden on the Iranian economy ((M&PO) 1991). The loss of output, destruction and draining of labour resources and scarce foreign reserves proved to be extremely costly (Mazarei 1996) with the Iranian government estimating the war damage at more than 400 million US dollars ((M&PO) 1991). As a result of these external and internal shocks, the Iranian GDP declined sharply in the late 1970s.

Figure 4.2 The trend of GDP of Iran per year in constant 2000 US$ (Billion US$) from 1974 to 2003



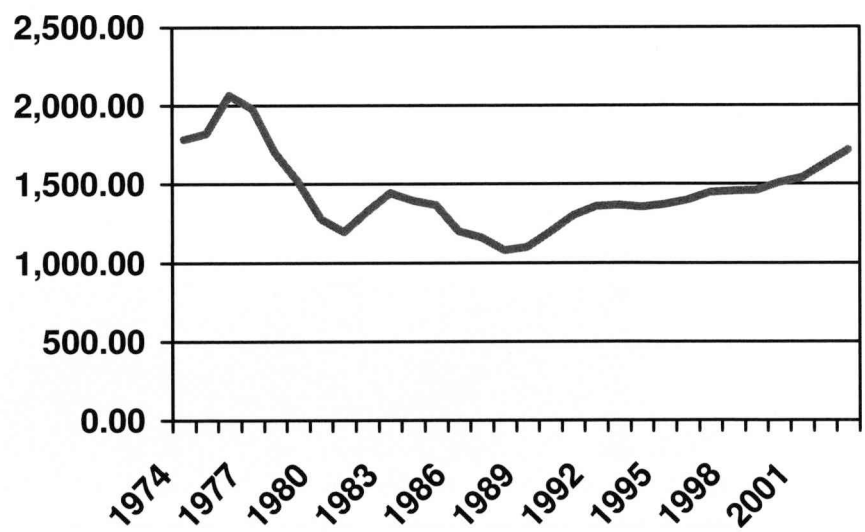
Data source: (World Development Indicators, 2004)

Figure 4.2 shows clearly the economic effects of the revolution and the war had on the GDP of Iran. GDP, measured in constant 2000 prices, fell to its minimum level in 1981 and stayed unstable until 1988. Since 1989, (the first year of the first five-year development plan), GDP showed a

stable growth up to 2003; almost doubling from $58.48 billion in 1989 to $113.88 billion in 2003.

The first five-year Economic, Social and Cultural development plan covered the period 1989/90 to 1993/94 and concentrated on the reconstruction and liberalization of the economy. The primary aim of the plan was to regenerate the economy, reconstruct the war-damaged regions, increase private investment, and initiate liberalization of foreign exchange and trade policy while aiming for an average annual growth of 8.1 percent ((M&PO) 1989). The average annual growth actually obtained was 7.3 percent, which is slightly under the plan's target (C.B.I 2006). The per capita GDP achieved in the second and third development plans reached $1.715.20 in 2003 (Figure 4.3) which is still below what it was in 1976 ($2.065.80) as population growth was greater than GDP growth.

Figure 4.3 The trend of GDP of Iranians per capita in constant 2002 US$ from 1974 to 2003



Data source: (World Development Indicators, 2004)

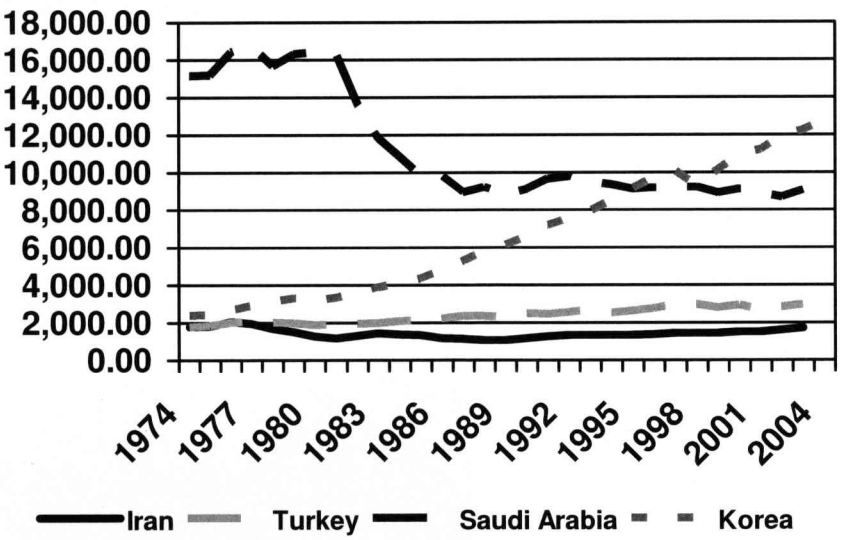
4.4 International comparisons

Comparing the growth performance of the Iran economy with other countries places the performance of the Iranian economy into an international context. Turkey and South Korea are chosen due to their

socioeconomic similarities to Iran in the mid-1970s (Figure 4.4) while Saudi Arabia is chosen as one of the middle income countries with high oil reserves.

In 1974 per capita GDP of Iran, Turkey and South Korea were $1,785.17, $1,790.95 and $ 2,396.78 respectively, but by 2003 the comparable figures were $1,715.20, 2,976.88 and 12,235.67 respectively emphasising the wide gap that had grown between Korea and the other two countries. Per capita GDP in Saudi Arabia was more than seven times higher than Iran, Turkey and Korea in 1974 but after a sharp decrease in the 1980s, it stayed stable during the 1990s and early 2000s at around $9,000.

Figure 4.4 The trend of the GDP per capita (constant 2000 US$) in Iran, Turkey, Republic of Korea and Saudi Arabia



Data source: World Development Indicators, 2004

4.5 Iranian demographic data

The Iranian population grew significantly in the 1970s and 1980s (Table 4.2) and although the results of the latest census in November 2006 have not been published yet, an unofficial announcement confirmed that the population had reached over 70 million for the first time. As the table shows the Iranian population increased by 3 percent in 1970s and, after a slight reduction, continued to increase by 3.9 in the first years of the

1980s. The growth rate started to decrease after 1986 (Table 4.2 and Figure 4.6). This high growth rate led to an increase of the population from 25,788,722 in 1966 to 60,055,488 in 1996 meaning that the Iranian population had doubled in less than two decades.

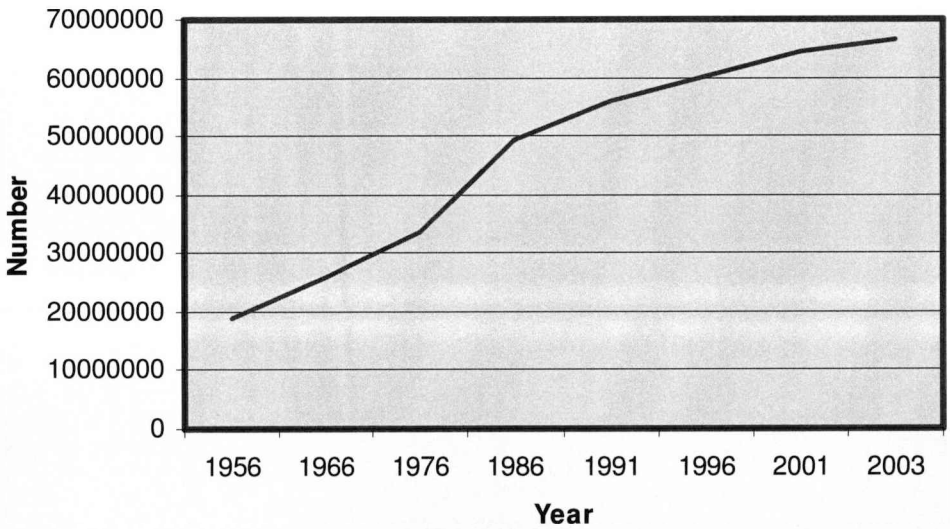
The sharp population growth rate in the 1980s resulted partly from improvements in public health (Table 4.2) and partly because of religious concerns about population control plans. Development in availability of clean water supply, national vaccination programmes, and providing general health information by Health and Literacy Crops (Pahlavi 1967) were important factors in developing public health in that time.

Table 4.2 Iranian population and its growth rates between 1956 and 2003

	1956	1966	1976	1986	1991	1996	2001	2003
Population	18954704	25788722	33708744	49445010	55837163	60055488	64528162	66479838
Rural	13001141	15284677	19045440	22349351	23172422	23026293	22700691	22107845
Urban	5953363	9794246	14494759	26844561	32385554	36817589	41827471	44371993
Growth Rate	3.1	3.1	2.7	3.9	2.5	1.5	---	1.4

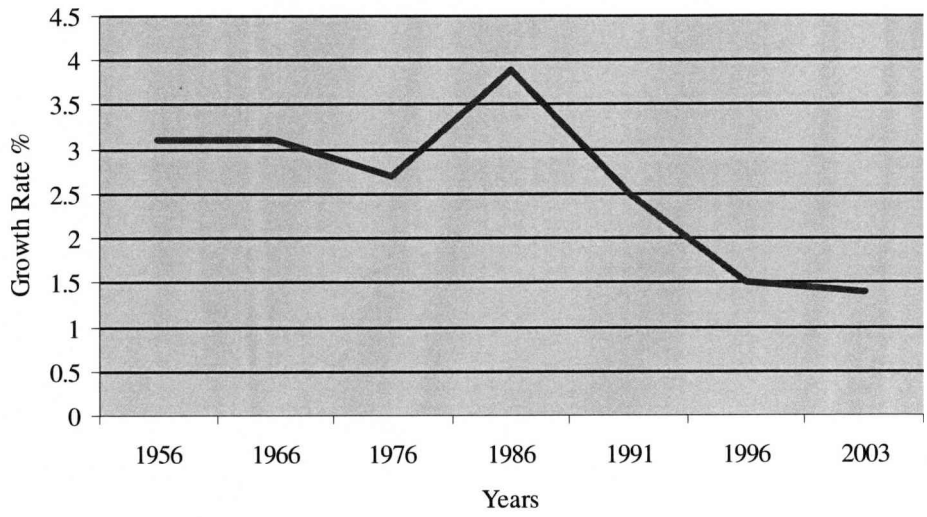
Data source: Iran's Statistical Centre, 2006

Figure 4.5 Iranian population between 1956 and 2003



Data source: Iran's Statistical Centre, 2006

Figure 4.6 Annual population growth rate (%), 1956-2003

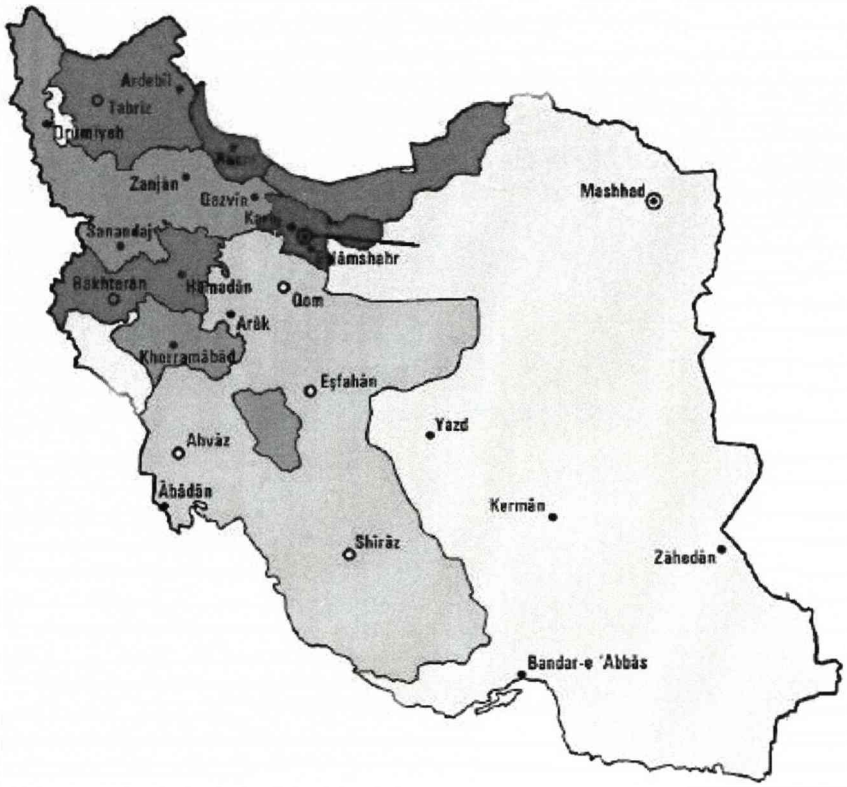


Data source: Iran's Statistical Centre, 2006

The most densely populated areas of Iran are the major cities, especially Tehran (Figure 4.7). In 2005 Iran had a population density of 42 people per sq km. Tehran province has the highest population density with 646 people per square kilometre, and South Khorasan the lowest with 7 people per square kilometre ((SCI) 2006).

The rapid growth in the Iranian population in the 1970s and 1980s has changed the age structure significantly (Figure 4.8) with 80% of the population being aged under 40. From a health perspective, this demographic pattern could be considered as an opportunity given that younger people and communities normally have better standards of health and place lower demands on medical services (Greenlick, Hurtado et al. 1968); (Young, Menken et al. 2006).

Figure 4.7 Distribution and density of Iranian population over the country

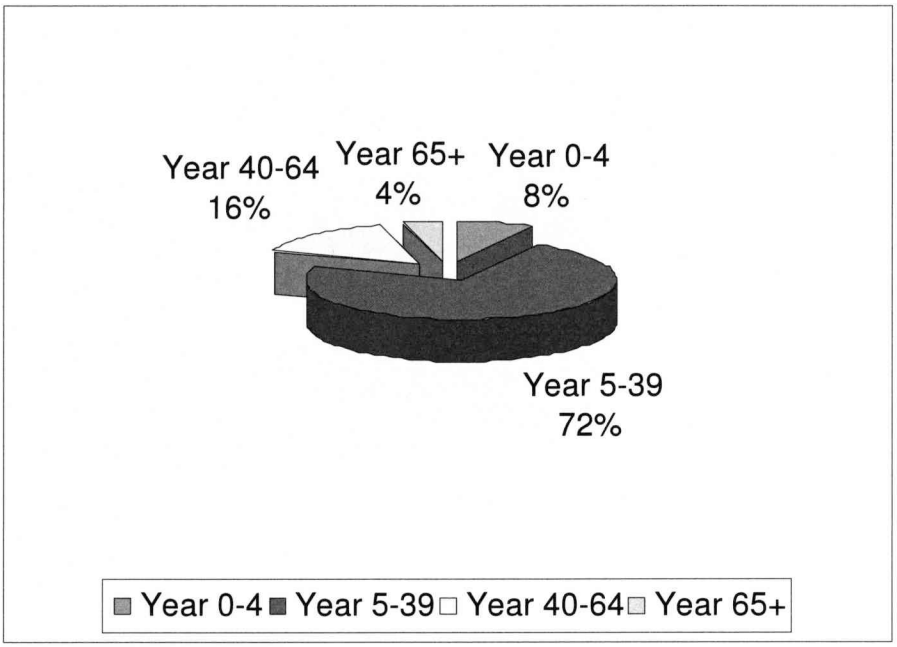


Data Source: Iran's Statistical Centre, 2006

A young population with the majority being of working age also provides significant economic opportunities (Forcese and Richer 1988) as young people are more productive and there are more workers to support less productive members of society. However, such a demographic structure also provides challenges as the demand for jobs and houses and other basic living needs are greatest amongst young people who are at the beginning of their lives.

In addition the structure of the Iranian population also impacts on the pattern of healthcare utilization in general. Figure 4.8 classifies the age structure of the Iranian population based on healthcare utilization. It is clear that the Iranian healthcare system is benefiting from the current structure of age groups in Iran but it is important to recognise that as the population ages, such advantages are likely to disappear.

Figure 4.8 Distribution of Iranian population by age groups



Source: Iran's Statistical Centre, 2003

It is also important to acknowledge the challenges provided by the "young population" in Iran (Sahraeyan 2006). The economy of Iran after the revolution was not strong enough to encompass the considerable numbers of individuals who were seeking work. The unemployment rate in 2004 was 19.6% (S.C.I 2006) and the implications of this high rate of unemployment are discussed in more depth in the following section.

Figure 4.9: The distribution of the Iranian population in urban and rural areas

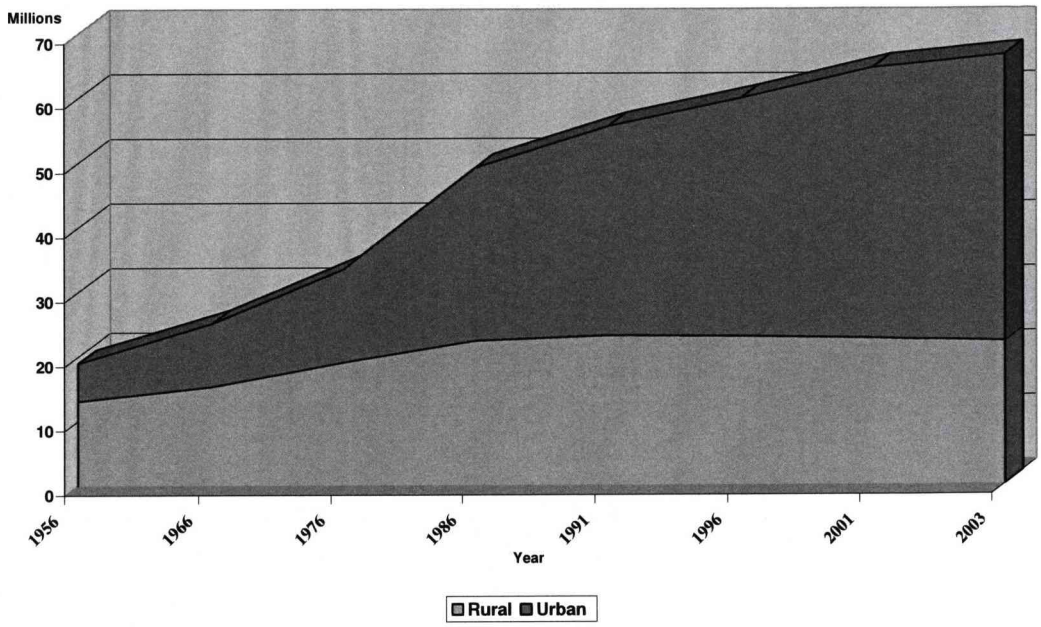


Figure 4.9 emphasises that the population growth in urban areas is far greater than in the rural areas. While 60% of the population lived in rural areas in 1976, nearly 70% of the population lived in urban areas by 2003. Two reasons can explain this event. The first is immigration of people from rural to urban areas to obtain better education, health, employment and a better standard of living (Amirahmadi and Manouchehr 1988). The second is the reclassification of cities, villages and towns between these two time periods ((SCI) 2006)..

4.6 Iran – an overview

Figure 4.8 shows that only 4% of the Iranian population were aged over 65 in 1996. Although it may have increased to 5-6% in recent years (estimated by ISC, 2006), it is clear that, in contrast to many developed countries, an aging population is not one of the urgent challenges confronting the Iranian health system.

Behdad stated that, in spite of initial improvements in income distribution immediately after the revolution, inequality in income within Iran has in

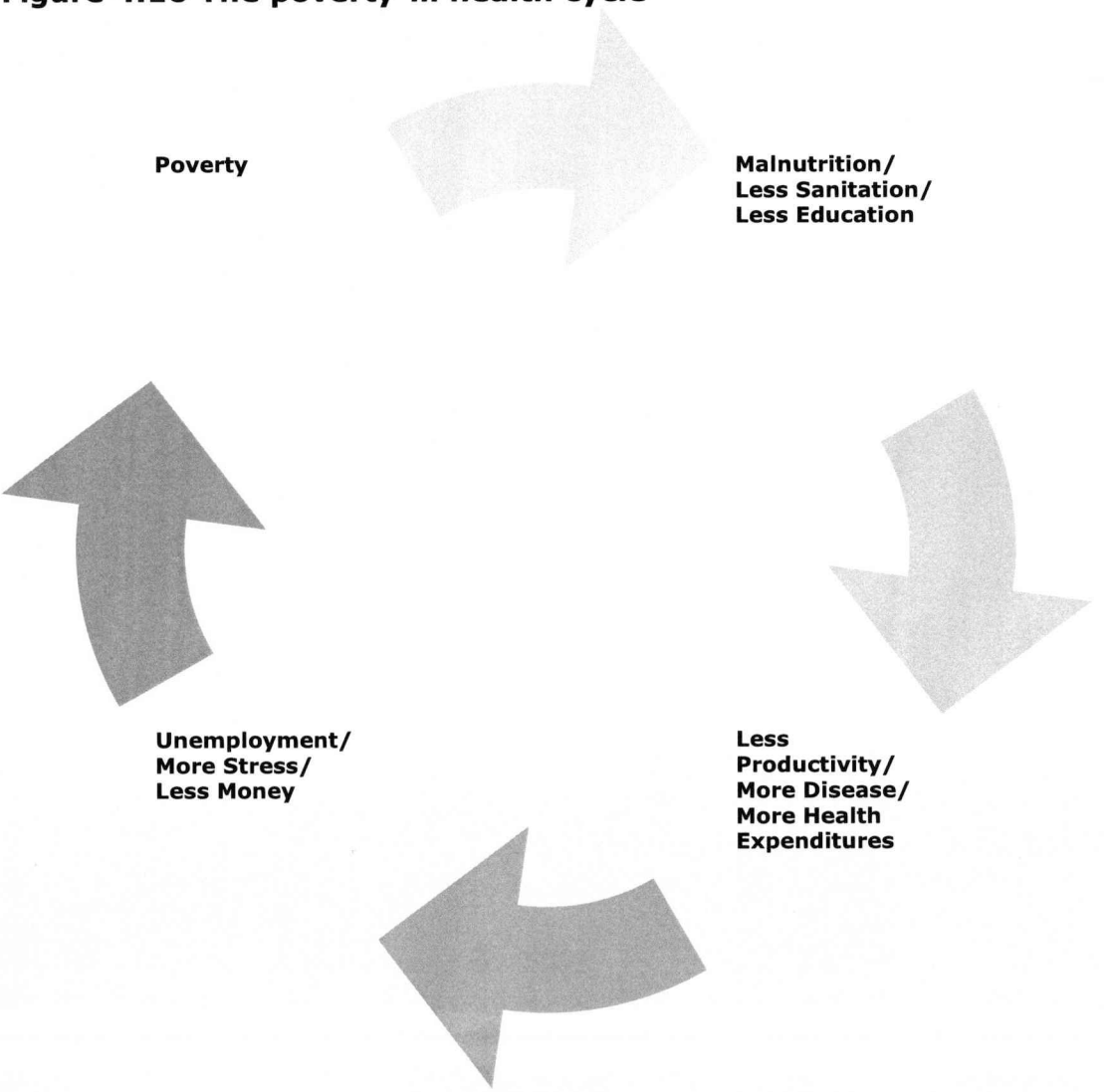
fact increased steadily since the early stage of the revolution (Behdad 1989). The precise definition and classification of poverty is still subject to debate (Foster 1998). "Relative Poverty" describes a person as poor in comparison to other members of their society. If the vast majority of people in a particular society have access to particular goods and services, e.g. telephone, car etc, the minority who are excluded from these goods and services on financial grounds can be said to be in relative poverty. Anyone without the minimum necessities or essentials for living is said to be in "Absolute Poverty" and is measured in relation to the cost of a basket of basic food and an allowance for non-food consumption (Lanjouw, Ravallion et al. 1996). The World Bank definition of poverty shows that whereas absolute poverty is based on a fixed poverty line, relative poverty is based on a poverty line that is relative to the distribution of welfare measured in the local area.

There are no precise and reliable statistics about the exact numbers and levels of poor people in Iran although it has been estimated that 25 million Iranians existed below the poverty line in 2003 (Khaliliyan 2005). In addition, there are substantial numbers that are on the border line and with a small reduction in income or increase in cost of living would fall below the poverty line. Estimates of absolute poverty range from 8 million (Navabpour 2005) to 10 million (Sadri 2005). Irrespective of the exact number of people, it is clear that substantial numbers of Iranians falls below the poverty line and that this will impose a significant burden on the Iranian health service.

The relationship between poverty and health has been studied extensively in various countries over a long period of time (James 1965); (Rockefeller 1965); (Straus 1965); (Antony and Rao 2007); (Das, Do et al. 2007); (Glassman and Bouillon 2007). It has been stated that there is a positive correlation between health and income (Cullhane 1997) as healthier people have better opportunities in work and more time to educate and increase their work's skills (Bloom and Canning 2000). However, this beneficial cycle can also operate in reverse. That is poor people who are not able to meet minimum standards in their diet will suffer poor health

which in turn will reduce their productivity and decrease their opportunity for work, further reducing their health. Figure 4.10 shows how the poverty-ill health cycle could potentially damage both health improvement and economic progress in Iran. Again, this emphasises the important interdependence between the health and economic wellbeing of Iranian society.

Figure 4.10 The poverty-ill health cycle



4.7 The Iranian healthcare system

The first part of this section describes the main components of the healthcare system and its history. The results of the interviews in

examining and explaining the internal structure, functions, and challenges of the health system are discussed in the next part of this section.

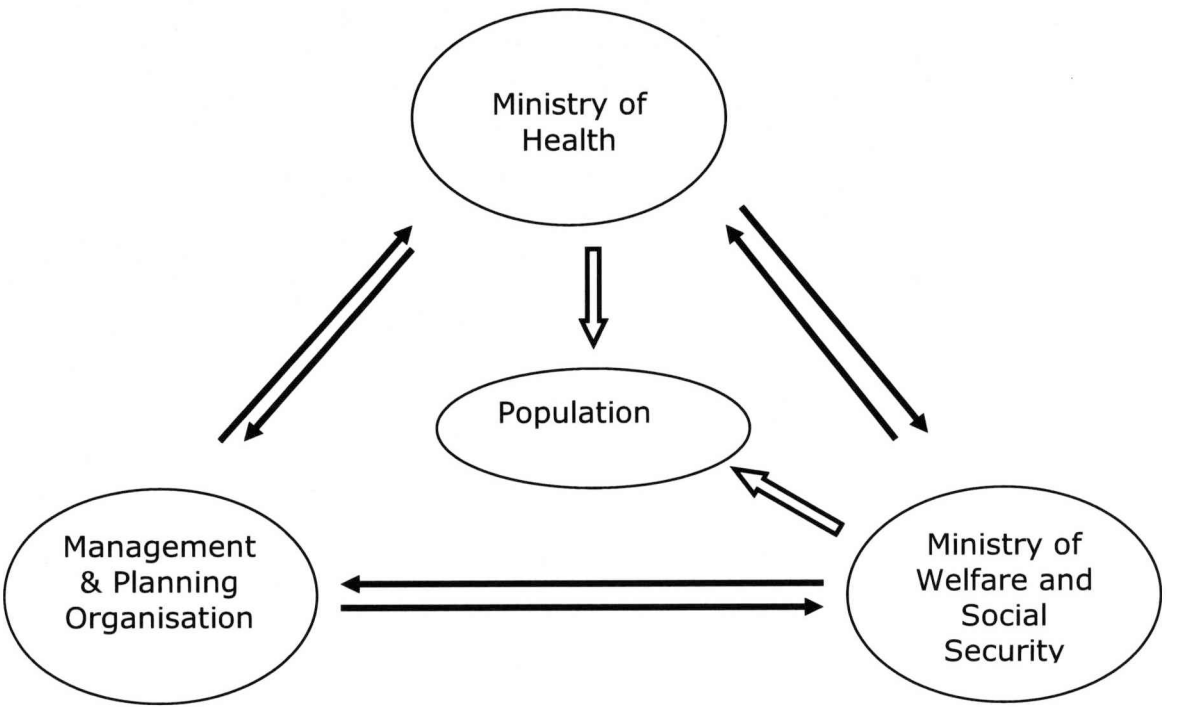
4.7.1 Structure of the healthcare system in Iran

The Healthcare System in Iran operates under the supervision of the Ministry of Health and Medical Education. The Ministry of Social Welfare and Management and Planning Organization also play essential roles within the healthcare system in Iran (Figure 4.11). The Health ministry consists of six deputies (Figure 4.12); the deputy of research and technology, deputy of health, deputy of employment, deputy of education and universities affairs, deputy of coordination and board of trustees, and deputy of management development and parliament affairs. It also consists of four organisations which are the Iranian Red Crescent Society, the Iranian Blood Transfusion Organisation, the Pasteur Institute of Iran, and the Social Welfare Organisation. Since 1985, medical universities have enjoyed the status of fully authorized representatives of the Ministry of Health at the provincial level in charge of two main tasks; medical education and the management of healthcare services (Larijani, Marandi et al. 1996). The deputies retain responsibility for providing and offering bureaucratic and specialist's services to the medical universities and other health related organisations at the provincial levels to ensure equity between provinces throughout the country.

The Iranian Red Crescent Society (IRCS) is the largest charitable society in Iran and its main aims are based on international conventions and contracts for International Red Cross. The IRCS provides support for injured and sick people during wars and disasters like earthquakes and floods, teaching first aid, and supporting and caring for orphans. Following the war, services provided by the IRCS have expanded considerably. The IRCS is now one of the main providers of pharmaceutical products and healthcare services in Iran. It expanded its activities to the preparation, distribution, and selling of medicines and also provides a wide range of modern and high technology services throughout Iran. It manages many rehabilitation centres, twenty-nine physiotherapy centres, thirteen

orthopaedic centres, the Iranian Helal (Crescent) Ophthalmology Centre and the Iranian Helal Dialysis services (I.R.C.S. 2005).

Figure 4.11 Structural relationship between Ministry of Health, Ministry of Welfare and Social Security, and Managing & Planning Organisation in planning and managing healthcare services



The Iranian Blood Transfusion Organisation (IBTO) is a non-profit network of blood centres in Iran established in 1974. The chief task of this organisation is to provide and maintain a safe and sufficient blood supply in accordance with international standards. However, this organisation also undertakes research on blood disorders (such as thalassaemia, haemophilia, and also various aspects of the immune System through its research department), clinical services (including genetics counselling, AIDS counselling, hepatitis counselling , thalassaemia counselling ,and Aphaeresis clinics) in addition to providing blood and blood products to hospitals and other health care centres. All of these services are free of charge and almost all blood donations in Iran are the result of voluntary donations (IBTO 2005).

The Pasteur Institute of Iran is one of the oldest institutes in Iran established in 1921. The aims of the Institute are the expansion of applied

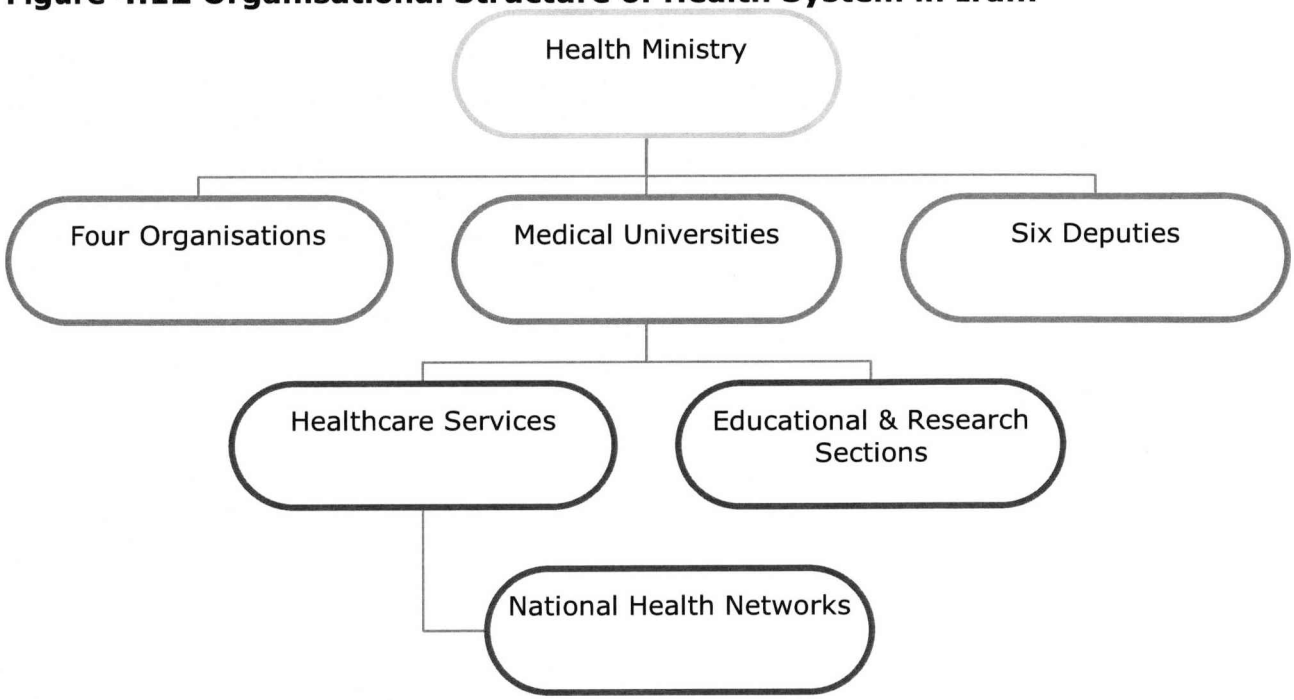
research on biological products, the expansion of research on basic sciences with an underlying aim of the introduction and optimization of new techniques and methods for use in applied research. The Institute has close and active collaborations with national and international universities and plays an important role in higher education and scientific research in the medical and paramedical fields in Iran (Pasteur-Institute 2006).

The Welfare Organisation (WO) was established in 1980 to provide basic services to develop material and spiritual rights of women, and to support and provide social security services for vulnerable individuals, particularly single mothers and orphans (Constitutional Expert Council 1979). Some of the main tasks of the Welfare Organisation are, therefore, supporting needy families, supporting orphans, supporting and caring for disabled people, supporting and caring for aging people and supporting withdrawing opium addicts. The Welfare Organisation developed by merging 16 organisations, societies, and centres that were working separately before development of the organisation. Figure 4.11 shows the structural organisation of the Ministry of Health.

The Ministry of Welfare and Social Security was created in 2005 and from this point, health insurance organisations came under management of this new ministry. There are four main health insurance organisations in Iran. The Social Security Insurance Organisation (SSIO) and the Medical Services Insurance Organisation (MSIO) cover around 80% of the insured population in Iran supported by the Imdad Committee Health Insurance (ICHI) and the Armed Forces Medical Services Insurance Organisation (AFMSIO). All of these organisations are managed by the Ministry of Welfare and Social Security.

The Management and Planning Organization is primarily responsible for planning, budgeting, and monitoring the performance of all governmental departments and preparing the country's annual programme and budget together with long term planning and budgeting for all governmental departments ((M&PO) 2006).

Figure 4.12 Organisational Structure of Health System in Iran:



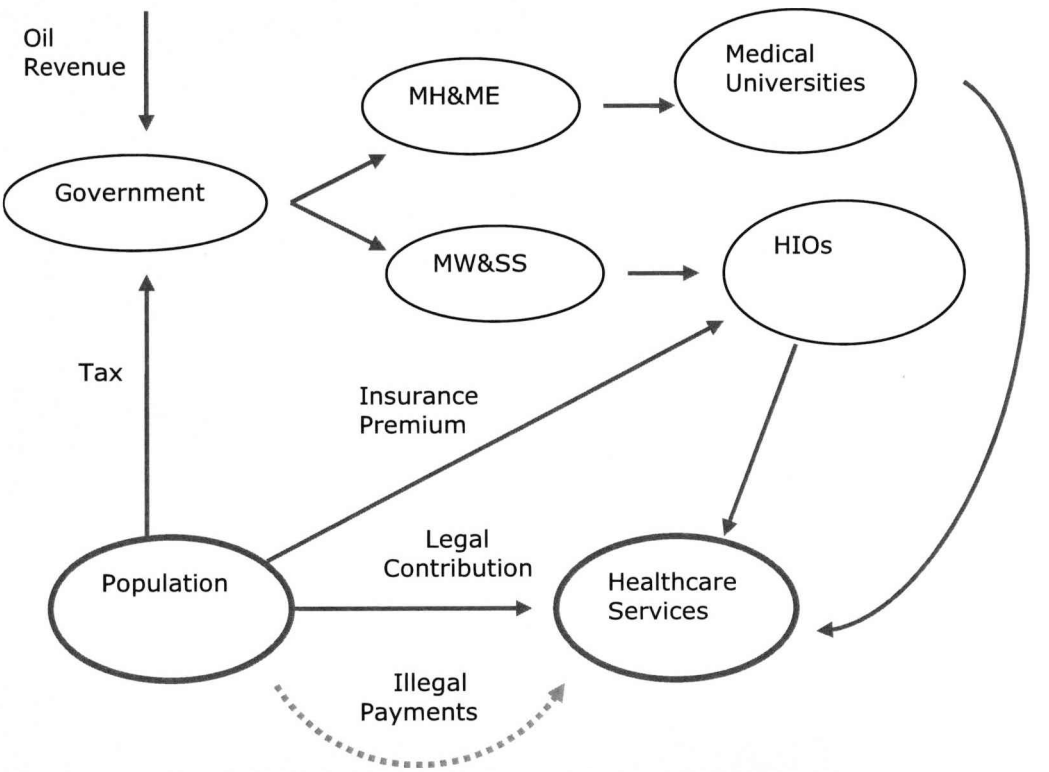
4.7.2 Healthcare financial structures in Iran

The healthcare system in Iran is managed centrally. The Ministry of Health and Medical Education (MH&ME) is in charge of planning, administration, regulating, and legislating for healthcare programmes with collaboration with relevant organisations and centres and supervision of the activities of regional health organisations and medical universities across the country. All medical universities, health related organisations and medical specialist's societies are involved in the planning and budgeting process but the role of the ministry and in particular the Management and Planning Organisation are fundamental.

Iran has three main sources of health care financing; general government budget, health insurance schemes, and individuals' out of pocket payments. The size of the budget for various services and activities of the ministry is decided by the M&PO in cooperation with the financial department of the MH&ME.

Patients' out of pocket payments for healthcare services come from statutory contributions in various healthcare services and from 'under the counter' payments particularly in secondary and tertiary healthcare services. A summary of the financial structure of healthcare in Iran is shown in Figure 4.13.

Figure 4.13 Financial relationships in the Iranian healthcare system



4.8 Health expenditure in Iran

Iran spent 31400 Billion Rials (equal to £2 Billion) on its health system in fiscal year 2004-05 ((MoH) 2005) equivalent to 6% of Iranian GDP (W.H.O. 2000). Although health expenditure in Iran has increased significantly in recent decades (S.C.I 2006), comparison with other Eastern Mediterranean Region countries shows that Iran has clearly fallen behind many of them in terms of total expenditure (Table 4.3) and it terms of per capita expenditures on health care (Table 4.4).

Table 4.3 Total expenditure on health in Iran as % of GDP, Compared with other countries in WHO Eastern Mediterranean Region

Country	Total expenditure on health as percentage of gross domestic product 2003
Lebanon	10.2
Jordan	9.4
Iran (Islamic Republic of)	6.5
Afghanistan	6.5
Egypt	5.8
Djibouti	5.7
Yemen	5.5
Tunisia	5.4
Syrian Arab Republic	5.1
Morocco	5.1
Sudan	4.3
Libyan Arab Jamahiriya	4.1
Bahrain	4.1
Saudi Arabia	4.0
Kuwait	3.5
United Arab Emirates	3.3
Oman	3.2
Qatar	2.7
Iraq	2.7
Pakistan	2.4
Somalia	n/a

Source: WHO Regional Office for Eastern Mediterranean Region

Table 4.4 Ordered per capita total expenditure on health in Iran in international dollars compared with other countries in WHO Eastern Mediterranean Region)

Country	Total expenditure on health as percentage of gross domestic product 2003
Bahrain	813
Lebanon	730
Qatar	685
United Arab Emirates	623
Saudi Arabia	578
Kuwait	567
Iran (Islamic Republic of)	498
Jordan	440
Oman	419
Tunisia	409
Libyan Arab Jamahiriya	327
Egypt	235
Morocco	218
Syrian Arab Republic	116
Yeman	89
Djibouti	72
Iraq	64
Sudan	54
Pakistan	48
Afghanistan	26
Somalia	n/a

Source: WHO Regional Office for Eastern Mediterranean Region

Table 4.5 Selected Ratio Indicators for Expenditures on Health

	1996	1997	1998	1999	2000	2001	2002	2003	2004	2005
THE* as % of GDP	4.9	5.5	5.9	6.1	5.6	6.0	6.0	6.7	6.6	7.8
GGHE** as % of THE	55.1	46.5	44.6	39.6	41.0	41.4	39.8	48.9	47.8	52.6
PSEH*** as % of THE	44.9	53.5	55.4	60.4	59.0	58.6	60.2	51.1	52.2	47.4
PH**** Out-of pocket as % PSEH	90.2	95.8	94.8	95.5	95.4	94.7	95.1	94.8	94.8	94.8

Data Source: World Health Organisation, 2006

* Total Health Expenditures on Health
** General Government Health Expenditures
*** Private Sector Expenditures on Health
**** Private Household

As shown in Table 4.5, private expenditure on healthcare services in Iran is very high. Reducing out of pocket expenditure is one of the priorities of the Ministry of Health over the next five years.

4.9 The structure of healthcare delivery in Iran

4.9.1 Primary healthcare services

Healthcare services in Iran are provided by both the state and private sectors. The state sector delivers preventive, primary and public healthcare services via the Health Networks (HNs) and university hospitals. The HNs provide mainly primary healthcares services and university hospitals supply secondary, and in some specific hospitals, tertiary healthcares services. The private sector delivers healthcare services via private hospitals, health centres and doctors surgeries.

Health Networks were established nationally in 1984 in order to:-

- Provide comprehensive access to healthcare services
- Provide equity of access to basic healthcare services
- Rationalise the basis of stratification of the healthcares (referral system)
- Provide healthcare services in rural areas
- Generate health information about the population (Shadpour 1994); (Larijani, Marandi et al. 1996).

Health houses are the smallest units within the health network. They provide its services in rural areas in three main sectors; family health, disease control, and environmental health services. Family healthcare services include prenatal, natal and postnatal care, care for children under five and of school-age, and immunization. Each household in the community has an individual file in the health house containing information such as sex, age, health status, previous major disease, special needs, and vaccination history. There are currently 15,651 active

health houses in Iran with one male and one female health worker employed in each health house.

A health house covers around 1,500 people, normally has 2-5 satellite villages and is supervised by the staff of Rural Health Centers. The rural health centres are village-based facilities, which operate with at least one physician, one health-technician, and 2-3 nurse-assistants. In addition to the supporting the health houses, they provide outpatient care and oral health services. Each rural health centre covers approximately 7,500 people and supervises 3-6 health houses. There are 2,343 active rural health centres in Iran.

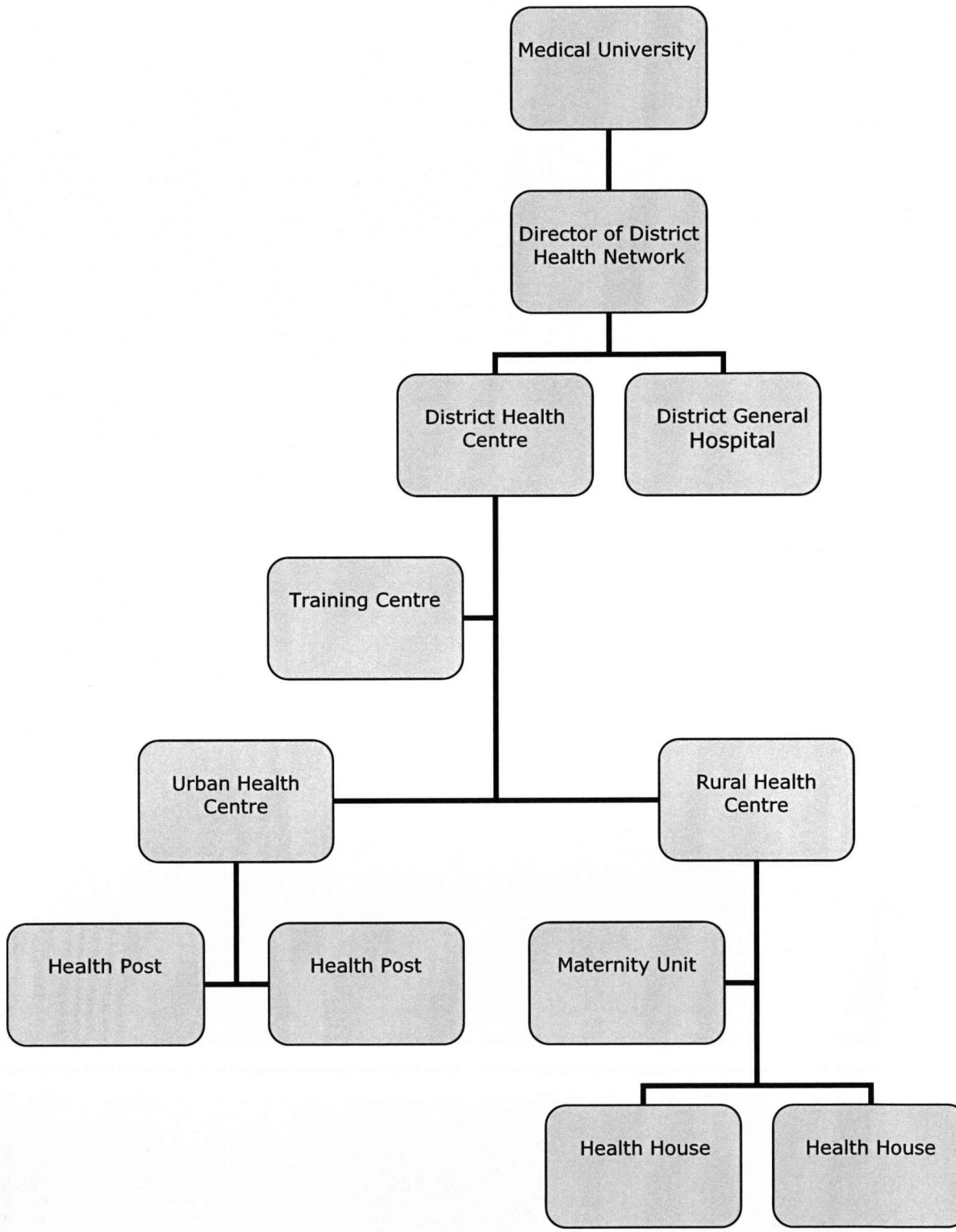
Urban health centres, UHC, are based in towns and are designed to cover approximately 60,000 people. The main duties of an UHC are to provide primary healthcare services and to refer patients as necessary to hospital services. The primary difference between urban and rural services is that in UHCs basic radiology services are also available. There are 333 active UHCs that each employs 2-3 physicians, one pharmacist, 3-5 midwives, 2-3 nurses and one laboratory technician.

The District Health Centre is a self-directed administrative unit responsible for planning, supervision and support of the activities of the health houses, rural and urban health centres, and health worker training centres. The health worker training centre provides local training for people who would like to work in health houses.

The Executive Board of the Regional Health Organisation supervises the activities of District Health networks and support health delivery facilities at the provincial level. The Executive director, deputy of Sanitation Affairs, deputy of Therapeutic Affairs, deputy of Food and Drug, and deputy of Financial and Administrative Affairs are the members of the Executive Board in the regional organisation. In most provinces, where the province has a Medical Sciences University, the chancellor of the university is the executive director of the Regional Health Organisation.

The establishment of HN's, particularly in rural areas has led to significant improvements in preventative and primary healthcare, leading to longer life and reductions in childhood and perinatal mortality. Figure 4.14 outlines the structure of healthcare provision in Iran.

Figure 4.14 Structure of Health Networks in public health in Iran



4.10 Health care delivery in practice: Interviewees responses

4.10.1 Achievements of the Iranian healthcare system

This section analyses the results of the section of the interviews relating to the achievements and challenges facing the healthcare system in Iran. The challenges facing Iranian healthcare arise in three areas; healthcare delivery system, healthcare financing, and healthcare management. Each section ends with an attempt to discern a consensus with regard to the points under discussion.

The interviewees' emphasise the recent achievements of the Iranian healthcare system in four areas; development of new Primary Health care (PHC) system; improvements in health insurance; controlling population growth rate; and integrating the medical education system with mainstream healthcare services.

4.10.2 Development of the new Primary Health Care (PHC)

Health status in Iran has improved significantly in the last three decades. The introduction of Health Networks (HNs) as the Primary Health Care structure (PHC) of Iran in 1984 resulted in significant reductions of mortality in children under five years of age. Dr Marandi, Ex-minister of health, expressed his philosophy of the PHC's first five years of operation.

> *"When we started the national health network in villages, the diseases began to reduce and the children mortality rates reduced considerably. So that, mortality rate of under-five children reduced from 36 thousands per 100 thousands people [36 %] to less than 3 thousands [30 %], in just five years. And of course the figure at the moment is even less than 1 thousand [10 %]. This sudden reduction at that time was a big step forward"* (Marandi).

Dr. 1, One of the senior policy makers of the Health system, believes that the main reason for this achievement by PHC was because it effectively targeted the key cause of childhood mortality.

> *"The PHC system is offering excellent services to villagers so that vaccination coverage in villages got even better than in the cities. The PHC has enabled us to control diarrhoea, respiratory disease, and infectious disease in villages, which were the main cause of the children's death at that time"* (Dr. 1).

One of the important advantages of the PHC system in Iran is its effective and active vaccination services as Dr. 2 director of a regional Health Network, and Dr. 1 emphasised. Dr 1 defined the meaning of "active services":-

> *"One of the important features of this system is its ACTIVE SERVICES. "Active PHC services" means that the system follows the individual's health plan. For instance, if parents or carers forget to follow one child's vaccination plan, one health worker go to the child's home to apply the vaccination"* (Dr. 1).

The availability of national health data is very important for both healthcare managers and healthcare researchers (Muir Gray 2001); (Palfrey, Phillips et al. 2004). The PHC system provides extensive health data about the Iranian population.

> *"Our health data base in villages is exceptional. We record all relevant information about each pregnant woman from the earliest days of the pregnancy and follow her up till the child gets to be six-year old. The information includes growth curve, weight, length, vaccination dates etc"* (Dr. 1).

Poor people are usually at higher risk of disease and one aim of health systems is to make healthcare services accessible to deprived and vulnerable individuals (Claeson and Waldman 2000).

> *"Our PHC system is fairly a unique one over the world. W.H.O. acknowledges our PHC system as one of the best rural health systems and one of the best anti-poverty systems amongst the PHC systems in the world"* (Dr. 1).

Development of this structure of primary healthcare services therefore presented an important step forward within the healthcare delivery system in Iran.

4.10.3 Improvement in health insurance

Health insurance in Iran has improved considerably since 1995 despite serious challenges from the limitation of resources and increasing health expenditures. Further details of health insurance organisations and policies are evaluated and discussed in Chapter 5 and so are not explored in this chapter.

4.10.4 Population growth rate control

Uncontrolled population growth negatively affects the economy, education and health within society (Haines 2003); (Hogberg 2005). Reducing the population growth rate represented a vital task for health policy makers. However, within the context of Iranian society, even talking about this issue presented challenges as Dr Marandi, deputy minister of health in those days, stated:

> *"I called up the growth rate control for first time after the revolution when I became deputy minister of health in 1983. The general concern of health policy makers was that this may not compatible with our religious beliefs. I understood later that I was very lucky I was not introduced as an apostate!"* (Marandi)

Because of such views (Amirahmadi and Manouchehr 1988), it was hard to debate the benefits arising from reducing population growth. Dr Marandi was almost alone in this matter.

> *"I used every opportunity to explain the problem to both decision makers and religious leaders. Finally I managed to get the cabinet agreement on growth control. But I still had lots of difficulties in practice. Ultimately I started the work on family planning with Imam Khomeini's green light"* (Marandi).

Over a period of years, the population growth rates reduced from 3.91% to 1.47%. Dr. 1 stated that this achievement resulted from a great success in family planning in Iran with the Family Planning Units in the PHC system being crucial in achieving this objective through teaching various types of contraceptive methods and offering services free of charge (Shadpour 1994). Dr Marandi received the United Nations Population Award in 1999 and WHO's Eastern Mediterranean Region's Shousha Award in 2000 for his activities in development of PHC and Family planning in Iran.

4.10.5 Integration of medical education and healthcare services

In 1985, the Ministry of Health was merged with the Medical Education section of the Ministry of Culture and Higher Education forming the "Ministry of Health, Therapeutics and Medical Education" (Larijani, Marandi et al. 1996). Before this integration, medical schools belonged to state universities and were under the management of the Ministry of Culture and Higher Education.

Integration of medical education with healthcare services organisations is still controversial and continues to be debated within the medical community. Dr Marandi was one of the strongest supporters of this policy and was the Minister of Health who managed to merge Medical Education to Healthcare Services Organisation. He believes that this integration has increased the advantages of both healthcare services as well as medical education.

> *"The implementation of this plan gathered all health relevant facilities and resources under one umbrella. This plan also improved medical education by providing the opportunity to increase the number of medical students and involving medical and health academics and students in diseases and health problems of our own country".* (Marandi)

One of the main reasons for merging health and medical education was the shortage of Iranian medical doctors.

> *"There were only 12-14 thousands Iranian doctors in country in 1980s. Although many foreign doctors were also serving in country, but, because of difference in culture and language of doctors and patients, their services were not easy and, in some cases, effective. The situation in medical professionals was even worse. There was not a gynaecologist in, for example Kordestan province. Many patients needed to come to Tehran for treatment. The waiting list for some medical professionals took months".* (Marandi)

This integration has increased the numbers of General Practitioners (GPs) and specialists and improved the level of health services in the country. However, this very success means that the health system now faces new challenges relating to unemployed GPs and difficulties in the medical education system. The extent to which these challenges originate from this integration is discussed later in this chapter.

4.11 Challenges to the healthcare system in Iran

4.11.1 Introduction

The Iranian healthcare system is currently confronted by a wide range of challenges. In this section, the current issues and difficulties associated with such challenges are extracted from the interviews and analysed. The need for national guidelines, the interface between primary and secondary

healthcare services and achieving equity in the healthcare delivery system were considered as the greatest challenges facing the healthcare delivery system by the interviewees.

4.11.2 Quality of healthcare services

Many health systems have developed methods to identify the best available health interventions that balance health gains with resource spending (NICE 2006). In Iran, however, there is not such a systematic approach to healthcare services and health technologies. Thus new and expensive technologies frequently become available without any evaluation. Dr 1 considers it as one of the quality problems of healthcare services.

> *"We have many difficulties in quality of medical services. The main problem is that there is not any national policy on health technology assessment and guidelines in the system. Every GP has authority to prescribe any new drugs, even if it is in the worst level of evidence. They probably think that this might be enough if just one medical journal mentioned it as effective method of treatment!"* (Dr. 1).

The shortage of financial resources is regarded as a further quality problem.

> *"The actual treatment expenditures are higher than official per capita expenditures. Therefore, state hospitals are not able to spend their resources as they would like. The quality of healthcare services, therefore, is sacrificed to keep the situation stable"* (Dr. 3).

The issues and challenges related to the primary/secondary interface are discussed below.

4.11.3 The need for improved co-ordination between primary and secondary services

Improving the coordination between primary and secondary healthcare services could help patients to follow up their health problem/s to secondary or tertiary cares if needed while preventing over utilization as in the UK where primary care physicians act as gate keepers to secondary care. The lack of systematic connection between primary and secondary healthcare services in Iran causes increasing pressures on the system. Dr 1 says:

> *"There is no systematic connection between level one and two in the national health network. This is very important particularly if you want to provide specific services for particular patient groups, such as, diabetics. The main reason for that is that we don't have gate keeper in our healthcare delivery system"* (Dr. 1).

Dr. 3 considered this problem may impose an extra cost on both the patients and the government.

> *"One of the important challenges of our health system is lack of healthcare services stratification. That is a patient could go directly to any doctors or specialist base on his/her decision. This poses an extra cost to both the patient and the government"* (Dr. 3).

The extra cost for patients and health insurers comes about through an inappropriate selection of doctors and specialists. This lack of systematic connection between primary and secondary care therefore imposes both quality and financial problems upon the health system. This matter is discussed in greater detail in Chapter 5.

4.11.4 The need for improvements in hospital services

There are two types of hospitals in Iran; state hospitals (university hospitals) and private hospitals. All state hospital staff receives their

salary from the medical universities but the Ministry of Health determines the price of services for both private and university hospitals.

The role of state hospitals is vital in secondary healthcare services in Iran as the numbers of private hospitals are not large and the prices of services in private hospitals are several times higher than the state hospitals, so that it would be very hard for the majority of the population to use private hospitals. Hospital services could be evaluated from both the quantity and quality perspectives. From a quantity perspective, the numbers of hospitals and available beds have increased significantly over the last decades. Regarding the development of the hospitals in Iran, Dr. Marandi says:

> *"Development of new hospitals had a great growth after the 1979 revolution. The numbers of hospitals doubled. The numbers of hospital beds increased. Although they have not had a good distribution, but the investment on hospital generation was a right decision"* (Marandi).

However, the quality of services and the managerial efficiency of hospitals are more issues of debate. While Dr Marandi insists that the hospital expansion was a right decision, some argue against that. Dr. 3 stated that:

> *"Although the idea of hospital generation was good, but since many of them established without prior study, there are numbers of hospitals that are not cost-effective at all. There are also numbers of ratified hospitals which their process of building are stopped in the middle of the way!"* (Dr. 3).

In fact Dr. 3 believed that the rate of hospital development was greater than required:

> *"In some cases we founded that if we devote a helicopter to transfer patients from ...to the nearest modern hospital in ..., it*

would be more cost-effective than running a modern hospital in ... with limited numbers of patients" (Dr. 3).

He also added:

"The hospitals had become centres that consume huge amount of the healthcare budget but provided low quality services in both clinical and catering services" (Dr. 3).

In order to improve hospital management and increase quality of services in state hospitals, the Ministry of Health ratified the "self-management scheme" through which the ministry pays the staff's salaries but the hospital must pay all additional expenditure via their income from selling healthcare services. The hospital manager can also distribute any excess to hospital staff to increase their motivation to work more efficiently.

Despite the financial incentives and increasing of the managers' authority, the problem of poor quality and inefficiency still are continuing. Dr Marandi attributes these problems to the self-management policy for hospitals.

"Unfortunately a poor supportive system for state hospitals ruined all of these achievements. So, the situations of hospitals from the rate of bed occupancy and quality of services have decreased. This is mainly attributable to self-management policy for hospitals" (Marandi).

Dr. 4 also believes that the self-management scheme has not been successful. He believes that the scheme has also damaged the teaching activities of the state hospitals.

"We have two teaching hospitals which are in self-management scheme. Around 95 percent of patients have serious difficulties in their hospital expenditures. Self-management scheme is not a suitable scheme at least for deprived districts. We have no option

> *other than to spend lots of our general and current budget in hospitals to keep them active. Thus we will face with shortage of budget in educational activities"* (Dr. 4).

Dr. 5 attributes the problems faced by hospitals to unrealistic medical tariffs causing financial difficulties. The structure of medical tariffs (see Section 4.12.1) are determined by the Higher Insurance Committee and this subject is discussed in greater detail in 'Healthcare Financing'.

> *"The self-management scheme of hospitals has not successful so far. When the current medical tariffs turn into realistic medical tariffs this scheme will be successful"* (Dr. 5).

An additional essential issue relates to the relationship between state and private hospitals. Dr. 6 member of the National Hospital Affairs Society says:

> *"The states hospitals have faced lots of difficulties. Despite the fact that they have many good specialists and skilled human resources as well as high technologic equipment, these difficulties have influenced the quality of their services frequently. I think one of the most important difficulties of state's hospitals is working of medical doctors and paramedical staffs in both state and private hospitals simultaneously. This is sometimes as shameful as you can see a name of specialist on the shift workers of a state hospital and a private hospital at a same time!"* (Dr. 6).

He believes that the income gap between private and state hospitals are the main cause of the problem.

> *"Working of paramedical staffs in more than one working shift is usually the result of financial problem. They have to work for an extra working shift to cover their family expenditures. This condition exists in hospitals in a very complex way. The Ministry of Health is not able to improve the situation by itself. It needs the*

cabinet to decide and to do something to solve this problem" (Dr. 6).

The interviewees outlined a number of clinical difficulties, management challenges and financial problems facing hospital services. These issues are discussed below.

4.11.5 The need for enhanced equity in healthcare delivery

In Iran equity is one the major priorities of health policy. Dr Pezeshkian, Ex-minister of health, considers equity as providing an essential base for the Iranian health system.

"No basis is most important than equity in our health system" (Pezeshkiyan).

Despite having such a high priority, there remains within Iran an unequal distribution of healthcare facilities over the country. Dr. 3 believes that there are considerable disparities in distribution of healthcare facilities in various geographic areas.

"Generally speaking, the wealthier the province, the more healthcare facilities. The differences between the cities in the numbers of doctors, hospital beds, rehabilitation centres, and diagnostic facilities like radiography, clinical laboratories, C. T. scanners and MRI scanners are three to six times! Around 50 percents of medical specialists are in Tehran, alone!" (Dr 3).

Despite the development of many hospitals and health centres in recent decades there are still disparities in the availability of modern hospitals with basic services. Dr M. Akbari, ex-deputy minister of health stated that:

> *"There are 32 cities which have no hospitals at all, 172 cities with simply one teaching hospital each, 36 cities with just two hospitals each. In addition we have 31 hospitals with no general surgeon, 32 hospitals with no internal specialist, 32 hospitals with no gynaecologist, 28 hospitals with no paediatrics, and 21 hospitals with no anaesthetics"* (Akbari).

Dr 4 confirms the problem of unequal distribution of health services and attributes it to the shortage of financial resources.

> *"Our place in availability of healthcare services is not good at all. In fact availability of healthcare services has worsened in last years. The main reason for this problem is that the budget of health system has not increased as much as inflation growth and other health related costs. The second reason is attributable to unsuccessful completion of health insurance coverage and health insurance services. Indeed health insurance organisations could not meet their responsibilities perfectly. This in turn could be attributed to financial problems"* (Dr 4).

Unequal access to healthcare services also occurs due to variations in the inability to pay. Dr. 3 highlighted this problem and stated:

> *"At the present time, healthcare services are not equally available for all individuals. Many of medical services are concentrated in Tehran and some other big cities, while they are not available in smaller cities. The second important thing is that even in Tehran, many people are not able to use available healthcare services because of their financial difficulties or lack of health insurance coverage"* (Dr. 3)

These quotes emphasise the serious equity issues currently affecting the Iranian healthcare services. The issues of healthcare financing are discussed in greater detail in the next section. The healthcare delivery challenges identified in the interviews are summarised in Box 4.1.

Box 4.1 Summary of the challenges in healthcare services

- Lack of Family Doctor
- Lack of systematic connection between primary and secondary services
- Lack of national guidelines
- Lack of systematic health technology assessment
- Hospital challenges (Clinical, managerial, and financial)
- Unbalance distribution of healthcare services and health technologies
- Problem of equal access to secondary and tertiary healthcare services
- Shortage of available financial resources

4.11.6 Analysis of achievements and challenges facing the Iranian healthcare system

The interviewees emphasised a wide range of difficulties and challenges faced by the healthcare delivery system in Iran which are categorized in two clusters so that they can be discussed more effectively. The first set of the challenges are those that originate from the structure of the healthcare delivery system. Lack of family doctors and lack of systematic connection between primary and secondary services are of good example of structural problem within the Iranian health care system. The second set of challenges include the issues which are attributable to policy and management. Method of health technology management, quality assurance of healthcare services, and accessibility to healthcare services for all are important policy challenges which are assessed against the three criteria of effectiveness, efficiency and equity. First the issues related to the structure of the healthcare delivery system are presented.

One of the important difficulties in the structure of the healthcare system is the 'lack of gate keeper' or family doctors, in the system. In the absence of family doctors, patients are allowed to select their doctors by their own value judgement. While this could be considered as a positive feature as it provides 'freedom of choice in healthcare' (Roemer 1991), it also reduces the degree of control that can be exercised over the Iranian healthcare system.

Iranian patients generally perceive specialists' knowledge to be superior to that of general practitioners and specialists are readily available in Iran. In addition, the price differentials between specialists and general practitioners are so low that patients prefer to be treated by a specialist rather than a general practitioner irrespective of whether they require access to such expertise. Further, the patient may choose to be treated by an inappropriate specialist given choosing the best specialist requires clinical expertise (Braunwald 2001).

From the supplier side's point of view, specialists need to satisfy their patients (customers) and meet their expectations to maximize their profit and to maintain their income especially given that patients appear to have enhanced expectations of specialists compared to general practitioners. This could, therefore, influence specialists' prescribing and lead to inappropriate and wasteful prescribing or inappropriate use of diagnostic technologies.

Optimizing the interface between primary and secondary healthcare is an important element in enhancing both the health of the population and the efficiency of resource utilization (Aday, Begley et al. 2004). In Iran, a lack of co ordination between primary and secondary healthcare services means that information about the patients' health history is limited (Jacobs and Rapoport 2004).

In effect, the Iranian healthcare system has no effective gatekeeper to control the interface between primary and secondary care, reducing the efficiency in utilization of financial and human resources within the health

system (Aday, Begley et al. 2004). Specialists are used in cases that could be treated easily by a general practitioner and inefficiency may also arise through the excessive and redundant utilization of expensive health technologies.

One of the important issues in healthcare policy is the lack of national guidance for assessing new and current health technologies. This can adversely affect the system by reducing quality of care as well as wasting available resources (Gafni and Birch 1983). Without an effective structure of HTA, it is stated that every physician can prescribe any new drugs irrespective of their clinical effectiveness. The lack of national clinical guidelines has left the way open to uncontrolled use of any medicine and therapeutic methods available within the healthcare market, potentially leading to high-cost wasteful healthcare services.

The interviewees stated that hospitals are not able to allocate their resources to provide high quality service, particularly in terms of inadequate salaries for healthcare professionals. Inadequate salaries require health professionals to work extra time in state or private hospitals. It is obvious that working extra shifts not only decreases the quality of care provided but also increases the risk of medical errors.

Many of the interviewees perceived that the current hospital difficulties originate from the under-funding of the self-management scheme due to unrealistic medical tariffs. The decreased hospital income from low tariffs is compounded by difficulties certain patients have in affording their financial contribution to hospitals, particularly in deprived cities and other areas. In addition to these difficulties, one of the important comments of the interviewees was the problem of surplus hospitals in some areas as some hospitals are established without prior needs assessment (Aday, Begley et al. 2004); (Walley, Haycox et al. 2004); (Donaldson, Gerard et al. 2005).

Providing access to healthcare for everyone who needs it is an important target for health systems throughout the world (W.H.O. 2000). While

establishment of HNs in 1984 improved availability of primary healthcare services to all Iranians, there are still serious and increasing concerns regarding availability of secondary and tertiary care throughout Iran. Unequal distribution of healthcare facilities and modern health technologies across the country is one of the key issues that arose in the interviews. There are wide divergences between medical facilities in Tehran and other cities in Iran. While there was one MRI, for example, for every 340,000 people in Tehran in 2006, there was one MRI for 2.4 million people in Sistan and Balouchestan province (Table 4.6, Figure 4.17 and Figure 4.18). That means patients who need to use some specific healthcare services may have had to travel to advantaged cities to gain access to treatment. In addition to unequal distribution of healthcare facilities, financial difficulties of healthcare consumers are recognised as the other important cause of unequal access to healthcare services. The issues related to financing of the healthcare services are discussed in the next section.

Health Technology Assessment (HTA) could help the healthcare delivery system in identifying and promoting cost effective care and helping to provide clinical and cost effectiveness guidelines for clinical decision-making. This could improve the quality of care and increase its resource efficiency.

4.12 Issues related to healthcare financing

Many challenges to the healthcare delivery system were attributed to the resource limitations inherent in the system by the interviewees. Health systems are not just concerned with improving people's health but with protecting them against the financial costs of illness (W.H.O. 2000). In addition to the subjects of this study, many of higher health authorities in Iran, such as Dr Lankarani, minister of health, Dr Fazel, ex-minister of Culture and Higher Education, and Dr Zafarghandi, the ex-chancellor of Tehran Medical University believe that the majority of challenges faced by

the Iranian health system originate from the economics of the healthcare system.

Dr Zafarghandi believes that without improvement in the economics of healthcare system it is not possible to successfully address the healthcare challenges.

> *"We are not able to improve our healthcare system other than to develop a referral scheme in our healthcare system. And we are not able to develop a referral scheme except to alter the economics of our health system to more sensible one. From economics of health I mean the share of government from healthcare expenditures"* (Zafarghabndi).

Dr Fazel judged that the lack of an economic approach in healthcare management, i.e. in determination of the Medical Tariffs, not only reduced the quality of care, but also compromised medical ethics.

> *"The lack of an economic approach to healthcare management has shifted doctors to disregard medical laws and ethics in many cases"* (Dr. Fazel).

Dr. Lankarani also accepts and confirms the economic challenges of health system. Though he didn't state anything about how best to confront the problem, he said:

> *"The economics of our health system is not acceptable at all. One of the worst examples is that each year 700 thousands people turn under poverty line because of their health expenditures"* (Lankarani).

Dr. 5 emphasised the many healthcare issues, like low per capita health expenditure, unrealistic medical tariffs, and health insurance challenges, originate from the lack of an economic approach to the system.

> *"There is no economic approach to healthcare system in Iran. This is why the economics of our healthcare system is ill. That is, per capita resources on health are far from real health expenditures of the population. And official medical tariffs are far from actual medical tariffs in the streets"* (Dr. 5).

The share of the GDP on health was also addressed. Dr 1 states that we are very far from the ideal position in this regard.

> *"We are now spending 5.5 percent of our GDP on health. Comparing with some equal countries, we feel that this is lower than ideal level. We are trying to increase this figure to 7.00 percent in next years"* (Dr. 1).

The pattern of resource spending at various levels of healthcare services is addressed by Dr. 7:

> *"We are spending 15-20 percent of our resources on primary healthcare services, 35-45 percent in secondary healthcare services and 35-45 percent on tertiary healthcare services. This pattern shows clearly that the economics of our system is wrong. I would like particularly focus on spending on tertiary healthcare services which is obviously a wrong trend"* (Dr. 7).

More details are also discussed later in this thesis.

4.12.1 Medical tariffs (medical fees)

Medical tariffs or medical fees are the prices of medical services which are suggested firstly by Management and Planning Organisation and Ministry of Health to Superior Insurance Council and then, after achieving a consensus within the Council, are submitted to the Cabinet for final approval. The details of members and responsibilities of the council are discussed in Chapter 5, where Health Insurance issues are discussed in greater detail.

As one of the features of Iranian healthcare system is freedom of choice in healthcare services, medical tariffs play a very important role in the system due to the Fee For Service (FFS) basis of the system, combined with the role and power of health insurance organisations in Iran. The FFS method has been recognised as a method that potentially could lead to over utilisation of health services. This particularly happens in systems with a lack of strong monitoring and inspection programmes. Dr. 1 explains this problem as follows.

> *"Our payment system is Fee For Services (FFS). Well, it is obvious that in such a system where we don't have family doctor, this type of payment cause over treatment problem. As an example you can see that when a general surgeon go to a city, numbers of appendectomy surgery increases sharply"* (Dr. 1).

The health insurance organisations also play a central role in determining medical tariffs in Iran as they are the main funder of the healthcare in Iran. They reimburse 75 and 90% of outpatient and inpatient services respectively. Thus it is obvious that any change in the level of medical tariffs will impose a significant impact on the health insurance organisations.

The government has tried to control medical tariffs by keeping them lower than the current market cost of the medical services. The low level of medical fees is one of the essential challenges for both healthcare providers as well as healthcare consumers as emphasised by Dr Sadr, Head of Medical Society in Iran:

> *"Medical tariffs at the moment are very far from real medical costs. The main request of Medical Society at the time being is to amend the medical tariffs to realistic ones. Reasonable medical tariffs lead per capita expenditures to more realistic ones. This could in turn influence the government budgeting and make the health budget more reasonable"* (Sadr 2005).

Increasing the level of medical tariffs would provide additional resources to manage healthcare services, so it is important to find out why medical tariffs appear to be below market price. One of the primary reasons is to minimize the financial pressure on both the population and the health insurance organisations. Dr. 7 believes that the government stopped increasing the medical fees simply because it perceived that medical salaries were adequate.

> *"In the war years from 1982 to 1992 the medical tariffs did not increase at all. The cabinet believed that the doctors should overlook their rights, may be because of their wealthy conditions! Increasing medical tariffs started from 1993. However, because of many factors they are still behind the true figures"* (Dr. 7).

Dr Fazel, ex-minister of Culture and Higher Education, attributes the problem to the process of medical tariffs determination. He believes that problem is caused because the major consumer of the healthcare services, the Higher Insurance Council (HIC), also decides the level of medical fees.

> *"Medical tariffs have never been realistic in last three decades. One of the essential reasons for this is that the Superior Insurance Council was to determine the medical tariffs; while almost all of the council's members were consumers of medical services. Therefore, it seems that they were not suitable references for determination of medical tariffs. Thus the unrealistic medical tariffs imposed to medical society in last years"* (Fazel).

Dr. 8 analyses the problem from a different perspective. He states that the gap between medical fees in private and state sections is too wide to be easily filled.

> *"Private medical tariffs are much higher than state medical tariffs, so that it is not possible to decrease the gap between the two even*

by increasing the states' medical tariffs. I mean, if we increase the states' sections tariffs, say 10 times, the private medical tariffs would be increased 100 times! This is why the main interest of individuals who are working in both public and private sector is to work in private section. Therefore, in practice when public hospitals are staffed by physicians and other health workers who are not interested to state's section, the public sector is not able to become health market controller and to keep the healthcare services costs in low level" (Dr. 8).

Considering that almost all of health insurance organisations enjoy governmental financial support, the question would be why health insurance organisations do not agree to make medical tariffs more realistic. Dr. 9 attributes the problem to the limitation of health budget and low per capita health expenditures.

"Securing health of population is one of the responsibilities of the government. Achieving that the government must devote sufficient budget and true per capita on health, although this has not happened yet. Dedicating unrealistic per head on health leads to wrong medical tariffs. Doctors and other health workers in private sector have no option but to source their equipments, medicines and other things from free market. And when their incomes are not balanced with their costs, they have no option to compensate this with other ways, say under table fees. This is obvious that it is not possible to solve this problem with administration letters" (Dr. 9).

Dr. 9 provided a different perspective on the financial challenges of the system by introducing the concept of under the table fees. Dr Fazel states that unrealistic medical fees are the main reason for development of black market in medical services.

"These unrealistic tariffs in turn extended black market in medical services. Another unpleasant effect of impractical tariffs is sharing profit of medical services between medical workers. That means

doctors would benefit from recommending a laboratory test, radiography, CT or MRI Scan, while this is against our medical law as well as medical ethics" (Fazel).

4.12.2 Equity in financing

Fair financing in health systems means that the equitable costs of the health system are distributed according to ability to pay. According to the W.H.O. report in 2000, the index of Fair Financing Contribution (FFC) of Iranians on health for 1997 was estimated as 0.923, ranking Iran at 113 out of 191 countries. Dr.1 says:

"We have serious problems in fair financing contribution (FFC). One the most important challenges we faced is out of pocket expenditure of the people in treatment section. The share of this expenditure for people is now got to around 55 percent There are around 3 million people in Iran that spend between 40-50 percent of their income on their health expenditures. This figure is very dangerous. The point is that this population are both poor and ill" (Dr. 1).

Dr. 5 reinforced the views of Dr. 1 and emphasised that Iranian families spend a considerable proportion of their income on healthcare services.

"2.5 – 3.0 percent of Iranian families are spending 40 percent of their income on healthcare expenditures. According the fourth development plan, this number is targeted to reduce to 1.0 percent by the end of this plan" (Dr4).

Dr. 1 believes that under-table payment and uncovered medicines by health insurance organisations are two important causes of high levels of private expenditure.

> "There are many reasons for this increasing. The first important cause of this increasing is 'under table payment' to doctors. The second factor is uncovered medicines by health insurance organisations" (Dr. 1).

The impact of inequitable financing in the health system leads considerable numbers of Iranian families to fall below the poverty line because of their health expenditures. Dr Marandi says:

> *"Each year between 3.4 - 4.1 percent of Iranian families lose all of their assets to pay their health expenditures, according to the ministry of health statistics"* (Marandi).

Dr Lankarani confirms this problem:

> *"One of the worst examples is that each year 700 thousands people turn under poverty line because of their health expenditures"* (Lankarani).

Dr. 4 believes that increased individual health expenditure has imposed serious pressures on population numbers:

> *"Many families have problem in preparing their basic needs such as food and shelters. How can we expect them to pay 60 percent of their health expenditures directly"* (Dr. 4).

The fourth development plan aimed to reduce individuals' contribution in healthcare expenditure from 60 percent to 30 percent. However, the programme appears to be moving in the wrong direction. Dr. 9 said:

> *"The budget of ministry of health increased 6.5 percent, while the inflation rate is predicted at least 15 percent. Thus we are 50 percent behind inflation rate. Furthermore, the planning and management organisation and then the cabinet didn't accept per capita expenditure on health suggested by Higher Insurance*

Council, which was 7,000 Toman [1 Toman =10 Rials]. They reduced it to 3900 Toman for urban people and 1800 Toman for rural residents. Well, base on fourth development plan we are supposed to reduce the share of individuals on health expenditures 5 percent and increase the share of the government 5 percent to achieve the target by the end of the plan. However, the current trend shows that by the end of the programme the out of pocket expenditures of the population will get to 70 percent and the share of government will reduce to 30 percent" (Dr. 9).

These figures show that there is a serious shortage in public sector resources which has led some health professionals to emphasise the potential role of the private system. Dr. 3 believes that the private sector should be more active and should take more responsibilities on healthcare services.

"As health expenditures is the most problematic challenges of health system, and the government is not able to cover all of its expenditures because of limited resources, it is necessary to find a new way to meet up the financial needs of the system. We should redefine the private sector in health system. The cabinet should try, with its policies and plans, to activate private sector in providing healthcare services" (Dr. 3).

Dr Lankarani also believes that the private sector should take more responsibilities in the provision of healthcare services.

"The health sector is not comparable to any other sector and has no alternative. The government is not able to offer all of the services to people. Therefore, to increase the level of individual's health, it is necessary to use the benefit of private sector. Considering private sector more seriously could create new resources for health services" (Lankarani).

Identifying additional resources to fund healthcare services has been a major concern for all healthcare managers (W.H.O. 2000); (Donaldson and Gerard 2004). The issues relating to these factors are discussed in greater detail in the following section. The financial challenges facing the Iranian healthcare system are summarised in Box 4.2:

Box 4.2 Summary of the financial challenges faced by the Iranian healthcare system

- Lack of systematic economic approach to the health system
- Unacceptable expenditures patterns
- Method of payment to doctors
- Determination of Medical Tariffs
- Under the counter payments
- Significant amount of out of pocket expenditure

4.12.3 Analysis of issues relating to healthcare financing

The interviews emphasised the broad range of financial challenges currently facing the Iranian healthcare system. The important issue was perceived to be the lack of a systematic economic approach to the financing of healthcare.

Fee for services (FFS) payment methods are considered by the interviewees as one of the challenges in the financing of the system given that this method may induce demand for healthcare services (Donaldson and Gerard 2004). However, while certain studies show that FFS increases demand for services (Fuchs 1978); (Cromwell and Mitchell 1986); (Phelps 1986), some other studies argue that FFS has little impact on increasing healthcare demand (Vayda 1973); (McPherson 1981); (McPherson, Wennberg et al. 1982); (Vayda, Mindell et al. 1982); (Vayda, Barnsley et al. 1984). No detailed data is available regarding the impact of FFS on supplied induced demand in Iran.

Problems relating to the medical tariff were emphasised by many interviewees, both in terms of the process of medical fees approval and the method for establishing the level of fees. The process of fees authorization is compromised by the fact that the main consumers of medical services (the health insurance organisations) also exert a strong influence on the level of medical fees. The obvious incentive is to keep the medical tariffs as low as possible to prevent additional financial pressure on health insurance organisations. Unfortunately, inappropriately low medical tariffs can impose significant adverse effects on the healthcare system through decreasing the income of healthcare providers, thus providing further incentives towards supplier-induced demand. GPs may use their power to recommend or induce demand for their services in order to achieve a target income (Evans 1974). Thus, any under-pricing of fees may lead to greater provision of services in order to ensure that doctors achieve their target income.

Many interviewees also pointed to the existence of unofficial medical fees as an important consequence of the artificially low medical fees. Unofficial fees have been defined as: "payments to individuals or institutions in cash or in kind made outside official payment channels for services that are mean to be covered (without direct charge) by the public health care system." (Lewis 2000). The unofficial medical fees increase the likelihood of two negative consequences. Firstly, it may result in reduction of availability of healthcare services for patients who have difficulty affording such extra billing. Secondly, the unofficial payment increases the share of privately-borne payment as a proportion of healthcare expenditures. These two factors could adversely impact on both equity in finance and equity in access to healthcare services (Van Doorslaer, Wagstaff et al. 1993); (Aday, Begley et al. 2004); (Donaldson and Gerard 2004).

Sharing profits of medical services is also another method by which the income of health professionals in Iran can be increased. Sharing profits in this context means that the medical workers including doctors, clinical laboratories CT and MRI centres cooperate to increase their income via

mutual recommendation of services. The logical expectation of the process is increasing utilisation of medical services without any scientific and medical justification which reduces the efficiency of the health system (Aday, Begley et al. 2004); (Donaldson and Gerard 2004).

Some interviewees attributed the financial challenges to insufficient financial resources for health and therefore suggest providing opportunities for the private sector to play a stronger role in providing healthcare services. Nevertheless, the impact of private sector in this situation is open to question. This is firstly because the current healthcare market does not intend the private sector to invest more in providing healthcare services. Secondly, numbers of current difficulties stem from unregulated and out of control activities of the private sector in healthcare market. Thus it seems that giving more freedom to the private sector in providing healthcare services may even increase the severity of financial problems.

Health Technology Assessment could help Iranian health policy makers to target their limited resources on effective and cost effective health care services and consequently improve effectiveness and efficiency of the health system. This could in turn increase available financial resources to spend more on specific services or specific target population in order to improve equity in health and healthcare services. However, it is clear from the interviewees' responses that the system also requires reform in both the process and the methods of decision making

Although considerable numbers of the interviewees attributed the challenges of the system to the financial challenges and shortage of available resources for health care services, it would seem that the most difficulties of the system stem from healthcare management and healthcare policies. The next part of this chapter addresses such healthcare management challenges and difficulties.

4.13 Issues relating to healthcare management and policy

The opinions of the interviewees regarding the planning, policy and management of the Health System in Iran are presented in this section.

4.13.1 Health policy and planning

Almost all of the subjects stated that numerous healthcare challenges stem from healthcare management and policies. Some healthcare management difficulties are attributed to the Management and Planning Organisation. Dr Marandi, ex-minister of Health and Medical Education stated that:

> *"The main problem in healthcare management is in its macro-level management and particularly in Management and Planning Organization and its relationship with Ministry of Health. One of the important problems in macro-level management is lack of national and comprehensive outlook. There is no systematic cooperation and collaboration between various executive departments to improve the health of the community"* (Marandi).

Dr. 11, the budget manager of the health system, supports Dr. Marandi's idea on Management and Planning Organisation and says:

> *"They change the suggested plans from various departments and sections without very good and organised relationship. Therefore this is quite possible to get a financial support for an unnecessary plan or fail to get the support for a necessary programme"* (Dr. 11).

The method of management is the other concern in this field. Dr. Rezaei, Member of Parliament, states that we need to change and improve our traditional method of healthcare management; however he didn't state what he means exactly by "traditional methods".

> *"Management is one of the main challenges in our health system. It needs a serious reforms and changes. We can not achieve our Development Planes' target by this traditional method of management"* (Rezaei).

In addition to management's methods, Dr Rezaei believes that management's authority and shortage of resources also impose important problems. He adds:

> *"The second problem in the management is the manager authority. In many cases, because of some wrong regulation, a head of hospital has no authority to change even a porter of the hospital! The third factor affecting our healthcare management system is the amount of available resources. We should not expect a manager, even a very good one, to do a job of 10 Million [Rials] worth with just one Million [Rials]. When the available resources are limited, it is obvious that the quality of services would be the first item to be sacrificed"* (Rezaei).

One of the examples of unsuccessful management is the level of unmet targets that have occurred in the past three development plans. Dr Rezaei says:

> *"There were similar and repeated targets in the last three development plans simply because the system could not achieve its targets. There are many reasons for this. The first one is continues changes of managers in the system. The second one is economics' unsteadiness. And the third one is the opinion of the health minister. Changing the minister would result in the change in everything. This is why all four development plans are written almost similar and still many of their targets are unmet"* (Rezaei).

He believes that four development plans were written with similar targets because of crucial difficulties in healthcare management. He attributes

these issues to unstable management, strong dependency of implementation of programmes and plans on individuals, and the unstable economy in Iran.

4.13.2 The process of decision-making

Many parts of the health system suffer from the slow process of decision making in the system. Many healthcare managers complain of this problem. Dr 7 explains how prolongation of a decision can affect hospital performance and services.

> *"The Superior Insurance Council suggested 7000 Toman, as per capita expenditure on health for year 1385 (2006-2007), but the cabinet and the parliament didn't approve it and reduced it to 3890 Toman. This disagreement delayed the process of medical tariffs determination in turn and caused many problems for state hospitals consequently. That is, while the real costs of hospital's services have increased, health insurance organisations are reimbursing their financial documents based on last year tariffs. In addition, repayment of differences between new and old tariffs after a while, cause lots of administration and accounting works to both hospitals and health insurance organisations to audit the financial documents for a second time. Furthermore, one sources of hospital staffs' salary comes from receiving medical tariffs. Lack of sufficient financial resources influences on the payment to the hospital staffs, also. And this could, in turn, cause many other problems including reduction in quality of care"* (Dr. 8).

This example shows clearly how a long process of decision making could adversely affect the day to day running of hospitals and other service providers, leading to extra cost for the services provided.

4.13.3 New Technologies

A considerable proportion of the financial resources spent on new developments in health worldwide are used to acquire technologies.

WHO's Commission on Macroeconomics and Health reported that investment by developing countries in building basic health-care services, including the incorporation of reliable and safe health technologies, will be of huge benefit to health ((WHO) 2001). There is currently no systematic technology assessment in the healthcare system in Iran.

The main health challenge in new technologies in Iran is their level of utilisation and their distribution. Overuse of new technologies is one of the essential challenges of Iranian health system. Dr. Lankarani, Minister of Health, about the utilisation of the new technologies in Iran says:

> *"Utilization of MRI in our country is 2.5 times greater than Canadians"* (Lankarani, 2005).

Dr. Iraghizadeh, Dean of the Faculty of Medicine in Hormozgan Medical University, supports this view and adds:

> *"There are numbers of new health technologies like CT scanners in Iran, sometimes even more than some European countries. The case in our country is that these technologies are uses frequently without necessity"* (Iraghizadeh).

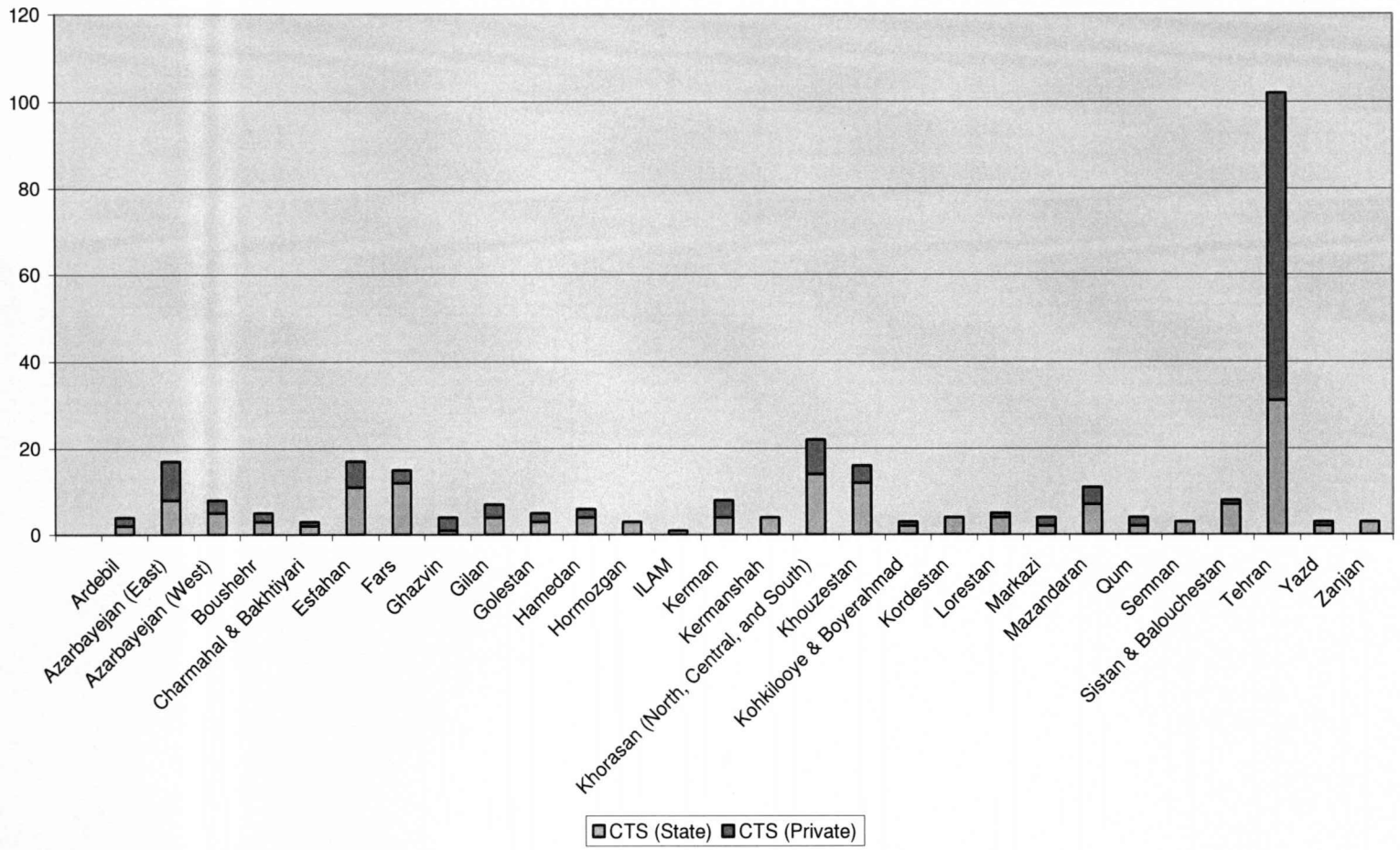
Table 4.6 provides the number and distribution of CT scanners and MRIs within the Iranian provinces. As the table shows, the numbers of these facilities in wealthy provinces, e.g. Tehran and eastern Azarbayjan are higher than the others and in particular the gap between Tehran and other cities is very wide. Availability of CT Scanners in Tehran is 5.5 times greater than in Western Azarbayjan (Figure 4.16). Variations of the distribution of MRIs are even greater than CT Scanners. Figure 4.18 shows that in Tehran there is one MRI for every 335,000 population, while in Sistan and Balouchestan province there is only one MRI for more than 2.4 million population.

Table 4.6 Number and distribution of CT Scanners and MRIs in Iran.

Province	CTS (State)	CTS (Private)	CTS Total	MRI (State)	MRI (Private)	MRI Total	Population	P/CT	P/MRI
Ardebil	2	2	4	1	0	1	1228155	307039	1228155
Azarbayejan (East)	8	9	17	1	3	4	3603456	211968	900864
Azarbayejan (West)	5	3	8	0	2	2	2873459	718365	1436730
Boushehr	3	2	5	1	0	1	886267	177253	886267
Charmahal & Bakhtiyari	2	1	3	1	0	1	857910	285970	857910
Esfahan	11	6	17	2	3	5	4559256	268192	911851
Fars	12	3	15	2	3	5	4336878	289125	867376
Ghazvin	1	3	4		1	1	1142656	285664	1142656
Gilan	4	3	7	1	2	3	2403716	343388	801239
Golestan	3	2	5		1	1	1616317	323263	1616317
Hamedan	4	2	6	1	1	2	1702456	283743	851228
Hormozgan	3	0	3	1	0	1	1403006	233834	1403006
ILAM	1	0	1	2	0	2	545787	545787	272894
Kerman	4	4	8	2	0	2	2651150	331394	1325575
Kermanshah	4	0	4	2	0	2	1878490	469622	939245
Khorasan (North, Central, and South)	14	8	22	2	3	5	7041071	320049	1408214
Khouzestan	12	4	16	3	2	5	4274979	267186	854996
Kohkilooye & Boyerahmad	2	1	3	1	0	1	633997	211332	633997
Kordestan	4	0	4	0	1	1	1439470	359868	1439470
Lorestan	4	1	5	0	2	2	1715710	343142	857855
Markazi	2	2	4	2	0	2	1350614	337654	675307
Mazandaran	7	4	11	2	2	4	2921041	265549	730260
Qum	2	2	4	0	1	1	1046239	261560	1046239
Semnan	3	0	3	1	0	1	589742	196581	589742
Sistan & Balouchestan	7	1	8	0	1	1	2405742	300718	2405742
Tehran	31	71	102	14	26	40	13422366	131592	335559
Yazd	2	1	3	0	1	1	990346	330115	990346
Zanjan	3	0	3	0	1	1	964601	321534	964601
Total	160	135	295	42	56	98	70495782	238969	719345

Data source: Ministry of Health, 2006; SCI, 2007

Figure 4.15 Number and distribution of CT Scanners in Iran; the share of state and private CT Scanners



Data Source; Iranian Ministry of Health, 2006)

Figure 4.16 Distribution of CT scanners in the provinces of Iran per population

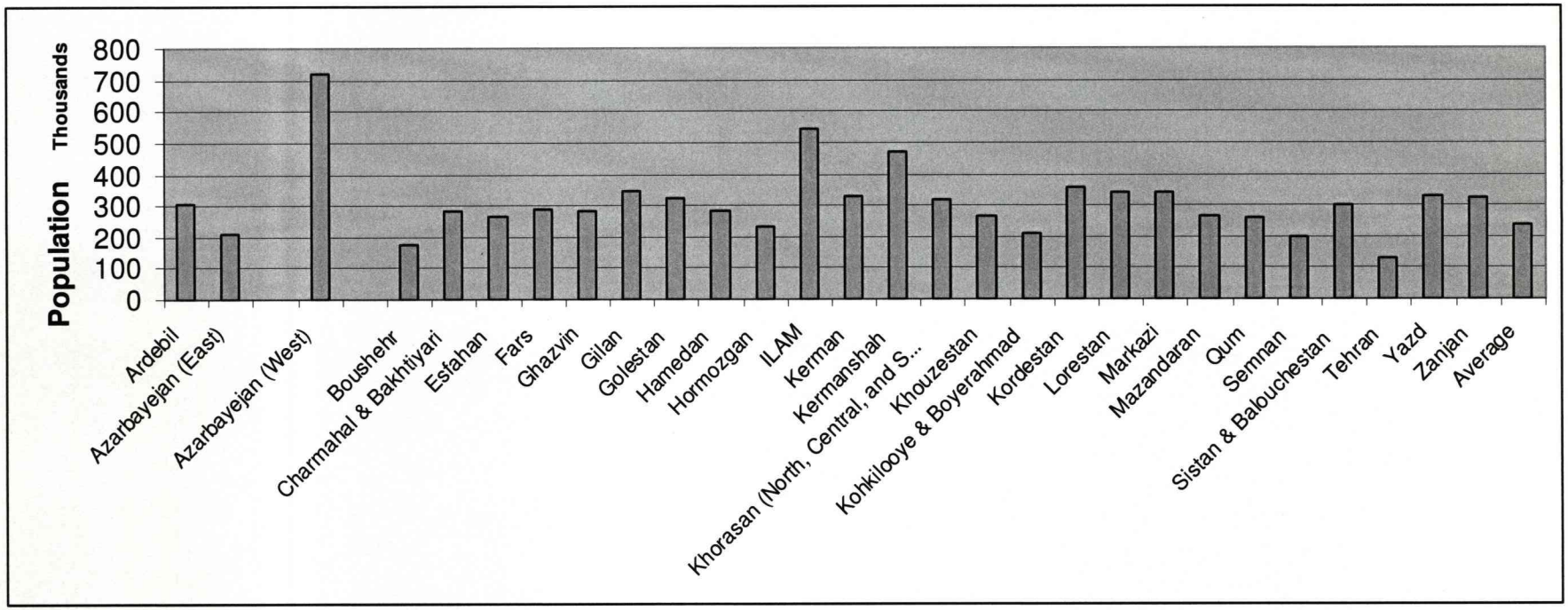
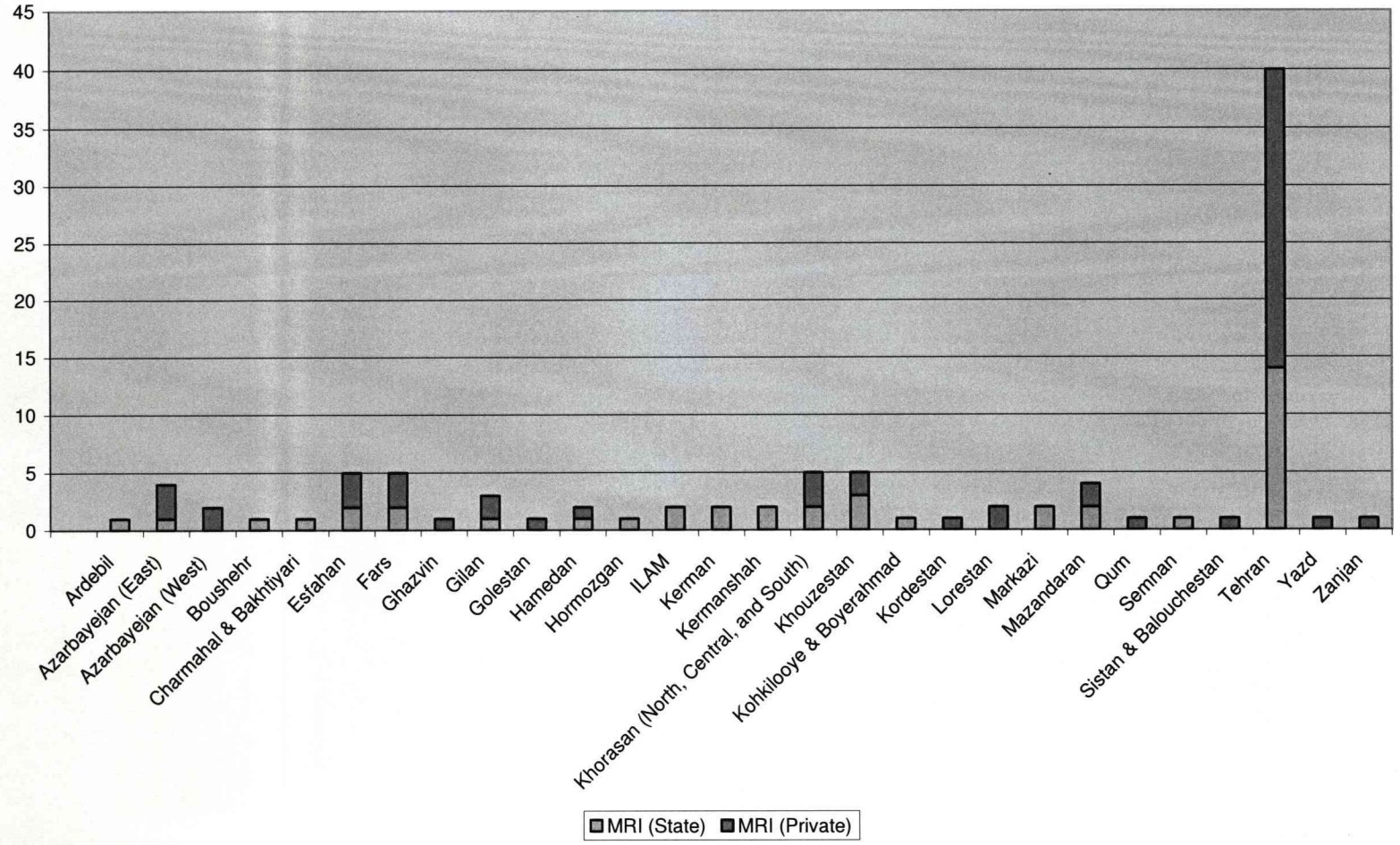
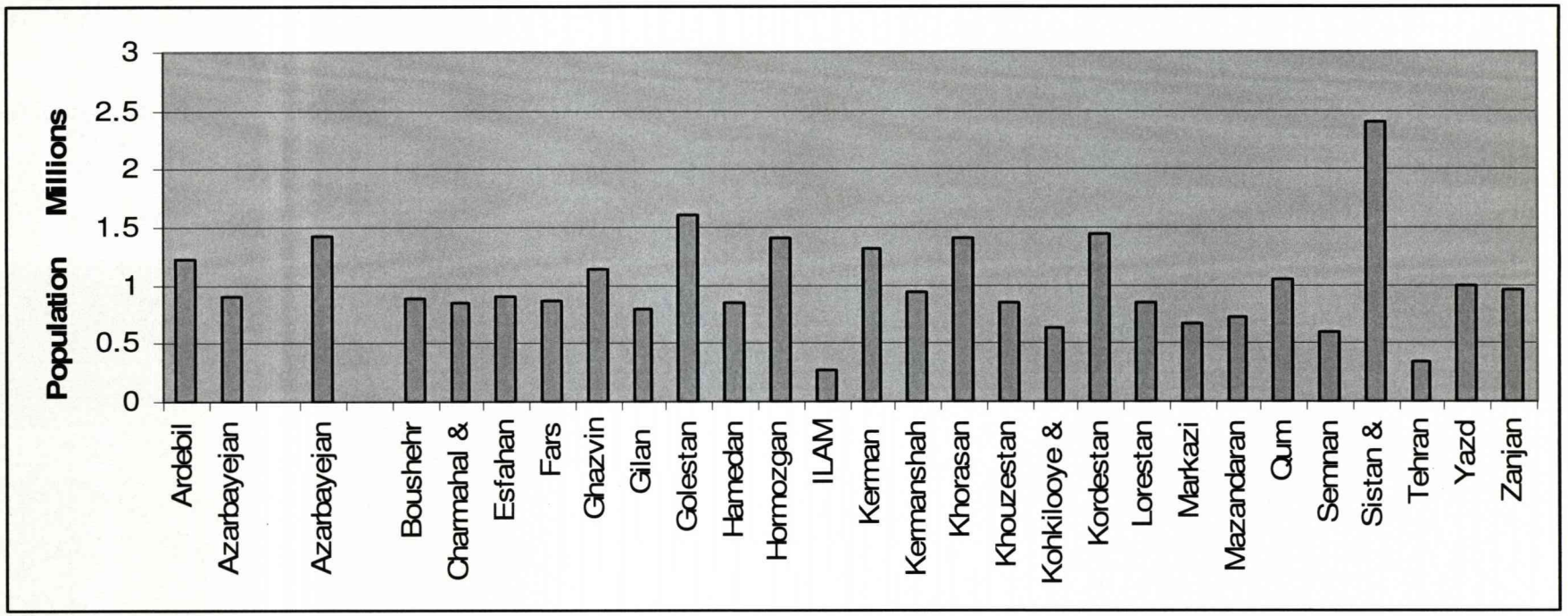


Figure 4.17 Numbers and distribution of MRI in Iran; the share of state and private MRIs



Data Source: Iranian Ministry of Health, 2006

Figure 4.18 Numbers and distribution of MRI per population in Iran



Dr. Akbari, ex-deputy of minister of health, believes that the share of total health expenditure devoted to new health technologies in Iran is much higher than in many other countries.

> *"At the time being we are spending 12 percent of our budget on imaging (radiographs CT Scanners, MRI), 11 percent on clinical laboratories, 8 percent on general human resources, and 8 percent on professional human resources. The pattern of spending in our country is different to many other countries. In other countries the share of human resources in budget is more than other parts. This pattern shows that we need to do some amendment to alter this pattern of spending"* (Akbari).

Despite the availability of high numbers of expensive technologies like CT scanner and MRI, there are still increasing pressures and requests for importing such technologies to Iran. Dr.1 relayed a surprising story about this:

> *"While we have faced with difficulties of overuse of modern and expensive technologies, there are various pressures for importing more technologies like MRI. Recently I realised that some companies are trying to import 40 MRI to Iran! This is surprising that when I asked the Cabinet to stop this process, they didn't agree with me at the beginning! Their primary argument was that when private sector wants to bring more health facilities for the population, why you want to stop them! After a long discussion and serious debates I finally managed to stop the process of importing"* (Dr. 1).

These declarations show that the health technologies in Iran do not appear currently to be managed efficiently. The Office of Medical Technologies in ministry of health, which is responsible for the importation of new technologies, is simply responsible for checking

the quality of the instrument, the price, and finally the maintenance services of the instruments after installation.

4.13.4 Personnel issues

Human resources are a central issue in health system planning and is a major concern for both developed and developing countries. Unemployment of physicians in Iran has caused pressures within the healthcare management system. Some healthcare managers believe that the main cause of unemployed doctors is their inequitable distribution, as they tend to be concentrated in large cities. Dr. 2 commented in this issue:

> *"The problem of unemployment of doctors and other medical workers is one of the noticeable challenges of our health system. I think this problem is partly because of unequal distribution of human resources in this field. Another important reason for such problem is an unequal distribution of some public services and sanitation"* (Dr. 2).

Dr. Panje Shahin, Chancellor of Shiraz Medical University, supported this view and added why doctors are not interested to serve in some areas.

> *"While in central cities we are suffering from overload of medical doctors, there is serious shortage of doctors in deprived areas. Doctors are not happy to stay in such areas when they finish their compulsory medical scheme. The main reason for that is limitations and even lack of social, educational and economic opportunities in these areas"* (Panjeshahin).

In addition to misdistribution of medical doctors, one of the underlying causes of unemployment is the lack of sufficient income for medical doctors.

> *"Many of our medical educated doctors have shifted their jobs to non-medical works simply because of insufficient income! This is while we still need their health services in many parts of our country"* (Dr. 2).

Dr. 5 supported this idea and added:

> *"50 percent of doctors are not able to save money for the future of their life and their children. Around 10,000 doctors are unemployed over the country. In addition, about 20,000 doctors have a non medical job to manage their current life expenditures"* (Dr. 5).

Dr. Lankarani supports this idea and adds:

> *"Only five percent of doctors are benefiting high income earners, while many of doctors are under poverty line, which is not acceptable at all"* (Lankarani).

The medical education system as a provider of medical doctors has a noticeable effect on the medical market. Dr. 2 attributes the case of unemployment of physicians to the policy of increasing number of medical doctors without any detailed planning of the workforce.

> *"In some periods many medical students were admitted to the universities without a detailed plan. In consequence, the society faced with problem of unemployment of doctors. Many of them could not get their job as they wished. This overloads of medical doctors imbalanced the equation of demand and supply"* (Dr. 2).

Dr. 1 supports this idea and adds that limitation of opportunities for higher education toward specialist and insufficient income are also important factors in this issue.

"Increasing numbers of GPs in recent years, limitation of acceptance and capacity of medical specialist divisions, and reduction income of medical doctors are three main reasons of turning GPs toward non-medical activities. Insufficient vacancies, low medical tariffs, and low interest of health insurance organisation to contract with young doctors, are of main factors of GPs reduction income. This income reduction has placed some GPs in under poverty line" (Dr. 1).

4.13.5 Medical education

One of the important goals underlying the merger of medical education with healthcare services was to increase both the quantity and quality of medical education in Iran. Achievement of both goals is now debatable. Dr Rezaei believes that the targets of medical education have still not been determined clearly which has affected the quality of medical education. He says:

"From quantity point of views, we had a great success. We developed one medical university in each province and increased the numbers of medical students so that the available doctors in the time being are able to cover all of the Iranian population across country. But from quality points of view we have many problems. One of the main problems is that the target of medical education has not defined clearly. This is not quite clear that whether a medical student trains to become a family doctor or an academic researcher" (Rezaei).

Dr. 6 challenges the current policy of medical universities as he believes that the number of medical students should be based on the need for doctors in society.

"Educating medical sciences must be based on the need for medical doctors, while when you note the current situation of

medical doctors in Iran you can see obviously that there has not been a good plan for this matter" (Dr. 6).

Dr. Fazel, ex-minister of Culture and Higher Education, and Dr. Malek Afzali, ex-minister of Health, are against the merging of medical education with the healthcare system. Dr Malek Afzali says:

"The main challenge of medical sciences universities is that they are belong to a ministry which has thousands of non-educative and non-research responsibilities and executive difficulties. Therefore, at the time being the first priority of medical sciences universities is not teaching and educating. The plan of integrating medical education with ministry of health was a wrong plan from the beginning. More than thousands of academics from medical education with various reasons expressed their disagreement with the plan at that time" (Malekafzali).

The combination of medical education with ministry of health appears to have adversely affected the quality of medical education. Dr Fazel says:

"The situations of teaching hospitals are not suitable for teaching at all, these days. While these hospitals have difficulties to organize their usual equipment, it is obvious that they are not able to provide a good teaching environment. Medical education should be returned to ministry of science and technology to keep the higher education integrative. The higher education must be integrated in a long term project" (Fazel).

Dr. 6 added that the combination of two main tasks to one ministry has made its responsibilities more complex.

> *"I believe that each ministry or organisation should have a clear responsibility. Ministry of science, research and technology is able to meet all needs of our country in terms of higher education and universities based on the fourth development plan. It has done its job very well so far and if there were any difficulties it could be because of some mismanagement and shortage of financial resources. Medical education and all other higher education must be centralised in one ministry. The importance of healthcare services, as a main responsibility of Ministry of Health, is become weaker than the time that medical education moved to this Ministry. Many members of parliament believe that medical education should go back under management of ministry of science, research and technology"* (Dr. 6).

Dr Toufighi, deputy Minister of science, research and technology, supports the idea of returning medical education to science and justifies it via the common roots of all sciences.

> *"It is necessary to return the medical education to ministry of sciences, research and technology. All of sciences have a common root and must communicate and collaborate with each other. According to worldwide experiences, the higher education must be integrated. Medical schools also like other schools are parts of integrated universities and communicate and collaborate with others. Many courses and basis of them are the same"* (Toufighi).

There are also many people who accept the difficulty of current medical education system, but believe that separating medical universities from healthcare services would not help at all. Dr. 3 said:

> *"This is true that from time that teaching and research materials were joined to healthcare services, education and research matters are sacrificed for healthcare service.*

However, one of the unpleasant methods of solving this problem is to disintegrate these from each other" (Dr. 3).

Dr. 8 attributes the current challenges of medical education to mismanaging the system.

"Many international communities are supporting the current system of medical education and healthcare system in Iran and many countries would like to transfer the experiences of Iran to their countries. There might be some difficulties in the current system because of some mismanagement which exist in other ministries, too. There are also many challenges in ministry of science, research and technology" (Dr. 8).

Despite the different perspectives, there is consensus on the existence of serious challenges in both medical education and medical services. The main issues in this field are summarised in Box 4.3.

Box 4.3 The Summary of policy, planning and management challenges of the system

- Poor cooperation and teamwork between the managers of the health system with managers and planners outside of the ministry
- Lack of evidence-based decision making
- Lack of healthcare priority league
- Poor health technology management
- Unstable management
- Unemployment of physicians
- Weak human resources management
- Medical education

4.13.6 Analysis of the issues relating to healthcare management and policy

A wide range of factors exerting direct and indirect impacts on the health system have been addressed by the interviewees relating to poor cooperation between health policy makers and national policy makers, issues related to medical education, unemployed physicians, and poor health technology management.

The processes and methods of decision making are two factors that received considerable attention in the interviews. In Iran, the process of decision-making is held to be indistinct given that the details of the division of responsibility and relationship between Management & Planning Organisation and Ministry of Health are not clear. In such circumstances, decisions become dependent on negotiation between powerful sectors or parties, rather than being based on a rational evaluation of the evidence. Furthermore, the lack of transparency in decision-making frequently leads to slow and late decisions which potentially increases the financial burden imposed on the health system (Aday, Begley et al. 2004); (Donaldson and Gerard 2004).

Managing new health technology presents a challenge to both developed and developing countries (Muir Gray 2001). While new expensive technologies have increased in recent years (Figure 4.15 and Figure 4.17), there is not still a clear and effective method of health technology assessment and management in Iran, particularly in imaging technologies such as CT Scanners and MRI. In many cases the availability of new technologies appear to be based not on the society's need, but rather the private sector appears to have created a demand for such technologies. In smaller and less wealthy cities, local political authorities demand for new technologies seems to be based largely on their desire to increase the availability of such technologies in their local area rather than on clinical need.

The adverse impact of unstable management is the other issue that frequently arose from the interviews. The frequent changing of healthcare managers has been highlighted as one of the factors that causes instability and problems in healthcare management due to the resulting lack of continuity. There is no doubt that the capacity, capability and motivation of managers exerts a significant impact on the progress of any plan. However, if health development plans are designed and monitored systematically, it should reduce the impact of unstable management (Walshe 2001); (Palfrey, Phillips et al. 2004).

Many comments related to medical education and its impact on the health system were raised by interviewees. The interviewees expressed differing opinions concerning the benefits of merging the medical education system with the healthcare services system. On one hand, it was argued that the integration not only has not led to the improvement of the quality of medical services and medical education, but has actually reduced both elements. In contrast, those in favour of the integration largely attribute the problems to other factors such as financial mismanagement. However, from the beginning the integration suffered from the lack of a detailed programme and evidence (Larijani, Marandi et al. 1996) and expanded the size and complexity of the ministry hugely.

Medical education currently appears to be training considerable numbers of medical students without having evaluated the need for such clinicians. The result is that there are currently considerable numbers of unemployed physicians in Iran due to excessive numbers of medical students and the imperfect distribution of physicians. The Ministry of health spends considerable amount of resources on training doctors, placing significant financial stress on the system without increasing the quality of care which is another example of allocative inefficiency in the Iranian health system (Aday, Begley et al. 2004); (Donaldson and Gerard 2004); (Haycox, Boland et al. 2004).

Though many health researchers have emphasised that healthcare systems are inherently complex and their management and planning is difficult (Walshe 2001); (Palfrey, Phillips et al. 2004); (Smith, Ginnely et al. 2005) it seems that in Iran the process of decision making is more indistinct and therefore inefficient. Applying HTA could help health decision makers in priority setting which could lead to a more efficient use of the limited healthcare resources available in the Iranian system. It could also help health care managers in managing new and existing high-cost technologies more effectively.

4.14 Conclusion

The Iranian health system has faced a wide range of challenges in the recent past with the establishment of family doctors as gatekeepers and developing a systematic connection between primary and secondary healthcare services being two of the structural-based factors which need urgent attention. Restructuring these factors could simultaneously enhance both the health of the population and the efficient use of financial and human resources within the Iranian health system.

In addition to the structural-based challenges there are also a range of policy-based issues which need urgent consideration. Lack of national guidelines for assessing new and current technologies, development of new health care services without prior needs assessment, lack of a systematic economic approach to financing of the health care services are all important policy-based challenges that reduce the efficiency and equity within the Iranian system.

The Iranian population is currently predominantly young and therefore the Iranian health system is not confronted with the problems associated with an ageing population. This provides a valuable opportunity for the health system to introduce reforms

which may help health system managers to run the system more effectively at a future time when an ageing Iranian population may exert greater levels of demand.

Health Technology Assessment could help Iranian health policy makers to target their limited resources efficiently by focussing on clinically and cost effective health interventions. It could also improve equity by allowing the health system to target subsidies more effectively to poor and disadvantaged families. The analysis of the interviewees' views emphasises that the process and the methods of decision making represent one of the main reasons for the current difficulties being faced by the Iranian healthcare system. Development of an Iranian HTA system should encourage the culture of evidence-based decision-making.

Development of a HTA system would need to take account of Iranian health insurance organisations and pharmaceutical regulations and industry. As such, it is necessary to examine these two sectors in Iran in order to assess whether a HTA system could help Iranian health system on improving effectiveness, efficiency and equity of its services. This assessment is undertaken in the following two chapters.

CHAPTER 5

HEALTH INSURANCE ORGANISATIONS IN IRAN

5 HEALTH INSURANCE ORGANISATIONS IN IRAN

5.1 Introduction

The Iranian health system is primarily an insurance based health system which represents an important influence on the Iranian healthcare system (Jacobs and Rapoport 2004). This chapter analyses the Iranian health insurance system and evaluates its performance with respect to the objectives of effectiveness, efficiency and equity of access to healthcare services in Iran.

5.2 History of health insurance in Iran

In 1947 the Iranian Tobacco Company insured their employees against health expenditure and health services. The first Labour Social Insurance law was legislated in 1952 when the Labour Social Insurance Organisation officially became part of the Ministry of Work and Social Services. The main objective of this organisation was to support workers against the financial difficulties imposed upon them by death, unemployment, or disability. In 1963, insurance coverage was extended to all members of the society, except those who were already covered by other insurance policies. The establishment of the Community of Welfare Centres in 1966 provided support in day care, family planning and maternal and child health care. A programme of intensive home visits was carried out to advise families to take advantage of family planning facilities (Prigmore Charles S 1976).

In 1974, the Ministry of Social Welfare was created to coordinate the previously dispersed activities relating to social welfare. All social welfare policies and programmes of government's ministries and departments, with those non-governmental organizations and agencies, were brought under the supervision of the High Council for Social Affairs. The Ministry of Social Welfare itself was subdivided into four-field-service organisations: the Social Security Organization, the Health Insurance and Medical Care

Organisation, the Rehabilitation Services Organisation, and the Social Welfare Services Organisation.

In 1975, the Social Security Law expanded the supportive services provided by insurance companies and made it compulsory for all workers to get insurance coverage from the Social Security Organisation. The revised law extended social security coverage to "all categories of government and non-government employees, workers, farmers, civil servants, professionals, and self-employed persons" and for the first time, the government began to pay a share of social security contributions. A total of 30% of the employee's wages was paid in the following proportions: government, 3%; employee, 7%; and employer 20% (Moarefi[1] 1975).

In 1979, the Iranian parliament merged the Ministry of Social Welfare into a newly-created Ministry of Health and Welfare and placed the Social Security Organisation under the management of this new Ministry. In 1980 this organisation was renamed the Social Security Insurance Organisation (SSIO) to emphasise its activity to health insurance services.

The Medical Services Insurance Organization (MSIO) was established in 1994 to cover individuals that were not eligible to be covered by other health insurance organisations (M.S.I.O. 2006) such as people in rural areas and the poor. From the introduction of this Public Health Insurance scheme, the proportion of the population covered by health insurance increased steadily. For example, the coverage rate of the rural population increased from 40% in 1994 to 85% by the end of 2004. In 2005, the Ministry of Welfare and Social Security was created to incorporate all health insurance organisations under its ministerial management.

5.3 Organisational structure of health insurance in Iran

Following the establishment of the Ministry of Welfare and Social Security (MWSS) in 2005, all health insurance organisations came under its

management. This Ministry is tasked to manage employment, health, housing and education affairs with the Ministry's main responsibility being to protect the underprivileged and to facilitate a greater participation of charity organisations in Iranian support and relief activities.

There are four main health insurance organisations in Iran, covering various parts of the society; Social Security Insurance Organisation (SSIO), Medical Services Insurance Organisation (MSIO), Army Forces Medical Services Insurance Organisation (AFMSIO), and Imdad (Relief) Committee Health Insurance (ICHI). All of them are government-run encompassing a range of benefit structures and contribution rates.

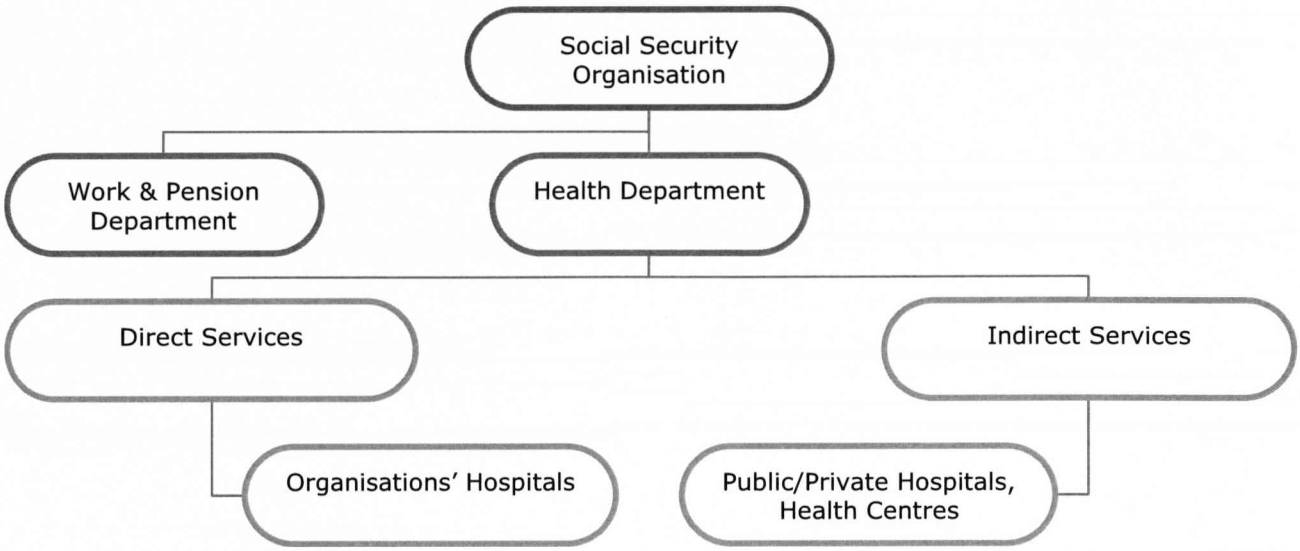
5.4 Social Security Insurance Organisation

The Social Security Insurance Organisation currently covers more than 27 million people across the country. Almost all of its customers are workers and employees in the private sector where coverage is compulsory by law.

The SSIO has two specific features which make it different to other health insurance organisations. Firstly, its financing system is largely independent from the government providing it with more freedom to manage its sources and services. Secondly, the organisation has two service departments that work alongside each other; the pensions department and the health department. The Health department acts as both a provider and a consumer of healthcare services. As a provider it provides services in its health centres and hospitals which are free of charge for SSIO insured people. As a consumer, the organisation pays 90% of inpatient and 70% of outpatient costs to healthcare providers who are contracted to the organisation.

The insurance premium of the SSIO is equal to 30% of salary with one-third supporting health and two-thirds supporting pensions. Figure 5.1 shows the structure of Social Security Insurance Organisation.

Figure 5.1 The Summarised Structure of Social Security Insurance Organisation



5.5 Medical Services Insurance Organisation

The Medical Services Insurance Organisation, MSIO, is the largest health insurance organisation in Iran, covering 38 million people in 2005 (M.S.I.O. 2006) largely as a result of the "Rural Insurance Scheme" (2003) which increased its coverage by around 18 million. According to this Scheme, all residents in rural areas and cities with less than 20,000 population were covered by this policy. The organisation has various types of insurance policy, with premiums being dependent on income levels. Governmental employees, those in rural areas and specific groups such as students receive government subsidies.

Table 5.1 shows the insurance accounts of MSIO and the level of subsidies that various groups receive.

Table 5.1 Existing Accounts of MSIO and their percent of subsidises and payments

Targeted Population	Insurance Premium		Patient Co-payment	
	Payment (Percent of PCHE*)	Subsidise (Percent of PCHE*)	Out-patient (Percent of Medical Fees)	In-patient (Percent of Hospital Fees)
Government employees	30	70	30	10
Rural People	20	80	30	10
Self-employed	100	00	30	25
Others**	20-50	80-50	30	10

*Per Capita Health Expenditure
** Others could be included University students, Religious School students and Martyr's families. A martyr is a person who was put to death or endured suffering because of his or her belief in Islam or Iran.

Imdad (Relief) Committee Health Insurance (ICHI) is a charity based health insurance body that was established a few days after the 1979 revolution to provide the basic level of insurance coverage to poor citizens who cannot afford to pay any insurance premium. Around 20% of its revenue comes from charitable donations and the government provides the rest.

The Armed Forces Medical Services Insurance Organisation (AFMSIO) covers around four million people in the armed forces and their families. Its services and policies are very similar to MSIO but it is funded directly by the Ministry of Defence.

Private insurance companies also provide policies that reimburse the co-payment share of patients' health expenditures which is 30% for outpatients and 10% for inpatients, in addition to providing certain services and facilities that main health insurance organisations do not cover. In addition to individuals, companies that want to provide their workers with a better health and social conditions packages may purchase private insurance policies for their workers.

5.6 The process of decision making in health insurance in Iran

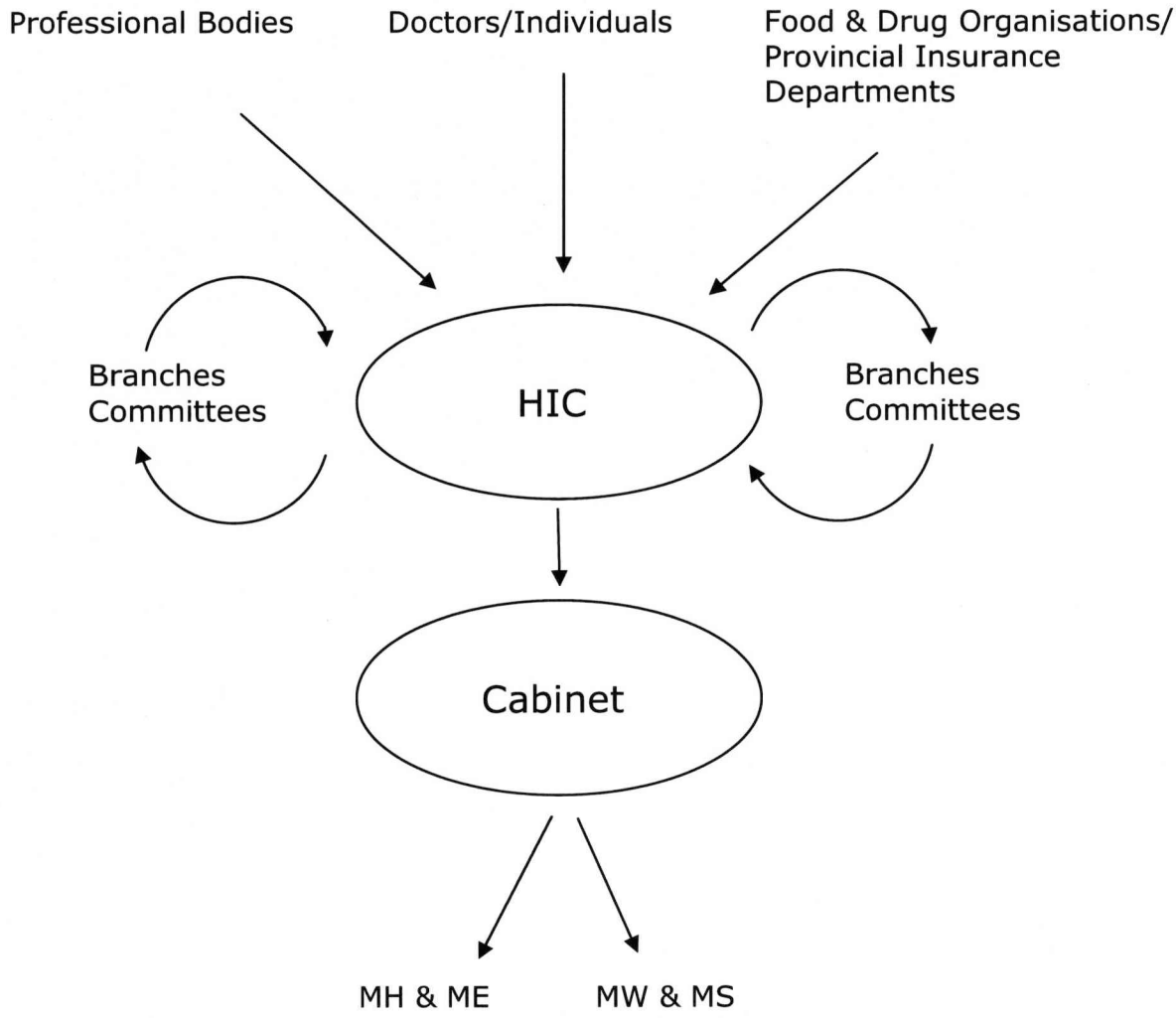
Policy with regard to health insurance is developed by the High Insurance Council (HIC) and communicated to all health insurance organisations to implement. The council was established in 1994 to undertake policy planning, coordinating and conducting, monitoring and evaluation of the quality and quantity of health insurance services provided to the population.

The Council has a wide range of duties. The main duties of the Council are:

- Determination of medical tariffs
- Determination of the level of insurance premiums and patient contributions
- Decisions relating to the inclusion or exclusion of medical services, medicines, diagnostic technologies and new technologies as part of the tariff structure

In deciding on which new health technologies to support, the views of specialists' societies and experts are sought. In many cases, specialists introduce new technologies to health insurance organisations and request insurance coverage prior to any form of assessment. The Sub-committee of Pharmaceuticals is responsible for collecting relevant information regarding the potential patients that may use the new technology and the costs imposed by the technology on health insurance organisations. The Council then decides whether to include the technology in the service package before transferring the decision to the Cabinet for ratification. At present this process take on average two years to complete and is outlined in Figure 5.2.

Figure 5.2 The Process of Decision Making in High Insurance Council



5.7 Health insurance system in practice – results from the interviews

Health insurance organisations have faced serious challenges and difficulties in recent years partly from internal policies and partly from external elements. The achievement of the health insurance system in Iran,l as perceived by the interviewees, are presented first followed by the perceived challenges and difficulties.

5.7.1 Health insurance achievements in Iran

Increasing coverage was considered as a major achievement of the health insurance system in Iran. Dr. 10 stated that:

> *"The numbers of insured people in last 25 years has increased from 40 percent to more than 85 percent of the population. This is while the number of the population also has increased from 35 million to nearly 70 million"* (Dr. 10).

This increase is particularly important when it is considered that this has happened mainly in rural areas, where the ability to pay is likely to be lower. Dr. 11 emphasised this and added:

> *"Considering vulnerable people started from the beginning days after the revolution. In fact, establishment of Imdad Committee a few days after the victory of the revolution shows that how important has been this matter for the leaders of the revolution. At the moment more than 80 percent of villagers are under health insurance policy"* (Dr. 11).

A major success of the Imdad Committee Health Insurance (ICHI) has been the establishment of a referral system for customers of the Committee. Dr 10 provided more detail:

> *"At the beginning years of the ICHI activities we were provided free health insurance package. That is, our consumer didn't pay any insurance premium to the Committee, any co-payment for their medicines and medical services. After a while we realised that we faced over demand and over utilisation of healthcare services. Then we decided to change our policy to a co-payment system. However, we soon realised that some of our insured people were not able even to pay their contribution for utilisation of services. This shifted us to apply the Family Doctor Scheme. We have been using this system from 7 years ago"* (Dr. 11).

The Family Doctor Scheme is a scheme whereby individuals have to register with a specific General Practitioner (GP) through which all primary care must be provided and through which the patient can be referred to hospital. Dr. 12 noted this achievement and added that the results of this scheme were amazing. He stated that:

> *"The results of the Family Doctor Scheme were wonderful! It reduced our expenditures sharply. In some general services such as GPs and simple diseases like common cold, we faced with 50 percent reduction in expenditures! However in professional and secondary healthcare services the reductions were varying between 5 to 20 percent"* (Dr. 12).

The Rural Insurance Scheme (RIS) has significantly expanded insurance coverage in rural areas while simultaneously establishing the Family Doctor Scheme. Dr. 13 stated that:

> *"In fact, through the execution of Rural Insurance Scheme the health system will achieve two important objectives. First, this could provide health insurance coverage for considerable numbers of individuals who have less access to developed healthcare services. Secondly, this could consider as a great and primary step toward "Family Doctor" scheme"* (Dr. 13).

Dr. Lankarani, Minister of Health, perceived the Rural Insurance Scheme as both an opportunity and threat for the Iranian Health System.

> *"The Rural Insurance scheme is one of the great opportunities for our health system. This is because we can develop it to rural areas and base our Family Doctor scheme on it. However, if we can not complete it in due time, for any reason, then we may face greater challenges for development of Family Doctor Scheme nationally"* (Dr. Lankarani, 2005).

However, one of the primary factors determining the success of RIS is ensuring sufficient availability of GPs in rural areas. Dr Lankarani stressed this difficulty:

> *"We have already covered around 90 percent of villagers. However, we have serious difficulties in finding the number of GPs who are happy to work to rural areas. This challenge is very important to us, because if the scheme is failed in rural areas, we may not able to establish "Family Doctor" scheme, also".*

5.7.2 Challenges, limitations and issues in health insurance services

Health insurance organisations face various challenges from the management, regulations, and policies of health insurance organizations; (Internal Elements) and from the structure of the healthcare system, the socioeconomic status of the population and a range of macro policies and decisions (External Elements).

5.7.2.1 Internal elements

Management and regulation

Each health insurance organisation has its own Management Board, director and organisational structure. Dr. 1 considered this to present serious problems:

> *"We have four different health insurance organisations. Four administrative structures, buildings, staffs, and so on. In addition they are not harmonized organizations. They are not in a same direction. Each of them goes its own way"* (Dr. 1).

Dr. 14 supported Dr 1's opinion and added that the existence of various health insurance organisations caused some other technical problems such as overlaps in coverage.

> *"Well, different insurance organisations have various levels of financial abilities. And then they offer different service packages. This makes individuals more interested to be covered by as many insurance policies as they can. This happens particularly in subsidised health insurance policies, such as Rural Insurance Scheme and Imdad Committee Health insurance, and Specific Patients health insurance policy"* (Dr. 14).

Specific Patients are defined as those suffering from specialist diseases such as thalassaemia, haemophilia, cancer and renal replacement therapy. All HIOs have subsidies policies for SPs with SSIO, for example, supporting 100% of pharmaceutical expenditures for specific patients. Dr 13 confirmed the problem of overlapping and added:

> *"We are losing our resources because of some parallel works and overlapping. For example based on the various organisations data, we have 40,000 Specific Patients in Iran. While we believe that the real figure should be around 27,000. We are spending around 1 million Tomans [Equal to £575 in 2005] for every single SP"* (Dr. 13).

Although he didn't support the figure of 27,000 with evidence, he added:

> *"Well, we don't have access to details information of other organisations, but our primary evaluations suggest that the actual figure should be around 27,000"* (Dr. 13).

Dr. 13 and 14 stated that information deficits arise because health insurance organisations do not share their enrolee's information with each other. Dr. 15 stated that:

> *"Our health insurance system is suffering from considerable degrees of overlapping. Health insurance organisations do not share their information with other organisations. In fact there is no systematic method for such cooperation. We hope that these*

difficulties will be solved with the establishment of Ministry of Welfare and Social Security" (Dr. 15).
(As explained in Chapter 3, majority of interviews are done in summer 2003, when MW&SS was in the process of establishment)

Overlapping may also occur between clients of the Rural Insurance Scheme in the insurance organisation of MSIO and clients of the ICHI. Dr. 11, from ICHI emphasised this problem:

"Many of our clients are using other health insurance policies, as well. For example there are some parents that their children are clients of SSIO or MSIO. Their children can officially consider their parents as their dependents and then can buy insurance policy for them for some additional cost, which is usually less than an independent person. However, if the same parents apply to be considered as an ICHI client, we must simply assess their socioeconomic status and may accept them as new consumers. We don't have any systematic tools to reveal such overlapping" (Dr. 11).

Dr. Moosavi, Managing Director of MSIO, confirmed problems relating to overlapping:

"Around 30 percent of the population are benefiting from multi health insurance policies".

Some people, however, have no insurance coverage. Although the exact figure of uninsured people is unknown, Dr Lankarani perceived that around 25% of Iranians has no health insurance coverage.

"25% of Iranian people have no health insurance coverage and therefore have faced serious problem on their health expenditures".

A concern about people who may not be able to attain any insurance coverage was also expressed by Dr 14:

> *"The point in subsidised insurance policies is that there are clear limitations for them. For example Imdad Committee Health Insurance has a specific budget to provide free of charge health insurance for vulnerable people. And if the applicants of such policy are more than the available resources, they can't be covered"* (Dr. 14).

Dr. 10 supported this idea and pointed to the numbers of individuals who are potentially eligible but due to limited resources could not be covered. Dr. 11 stated that.

> *"We are currently covered around 5 million peoples in our insurance organisations. This is while based on national statistics individuals who need such services are much more than that. There are no available resources to add any other persons at this time. The only way that one person can join the policy is that one person get out from the policy, by for example being economically strong enough, or going to better world!"* (Dr. 11)

There are around 10 million people defined as being in absolute poverty in Iran (Section 4.6) and these people are likely to be most in need of health insurance coverage.

As the SSIO has a fairly independent financial system which is based primarily on premiums, its financial difficulties are different from the other organisations according Dr. 14:

> *"The income system of SSIO is fairly independent from the government and is based on workers' salary. According the internal regulation of SSIO, we spend one third of the income on health and two third on pension and unemployment insurance services. Nonetheless, we have serious difficulties in the health insurance section financial resources. It is obvious that our expenditures on health have increased significantly"* (Dr. 14).

Dr. 13 pointed out this challenge and explained how difficult it is to reach a consensus in HIC.

> *"Whereas all three other organisations were supporting increasing per capita health expenditure in HIC, the representative of SSIO was against this decision! This is because SSIO is financially independent to the governmental per capita health expenditure. However, considering its influence on the Council, this made the situation difficult for us to increase per capita health expenditure to the level that we thought it should be. Nonetheless, the government later decreased even the result of HIC in that case. The final result of this process is that we will face more financial difficulties"* (Dr. 13).

The process of decision making has also imposed a significant impact on health insurance activities. The HIC was established to coordinate decisions between all stakeholders, however, there are still debates concerning the authority of the Council. Dr. 16 criticized the external elements that change the Council's decisions:

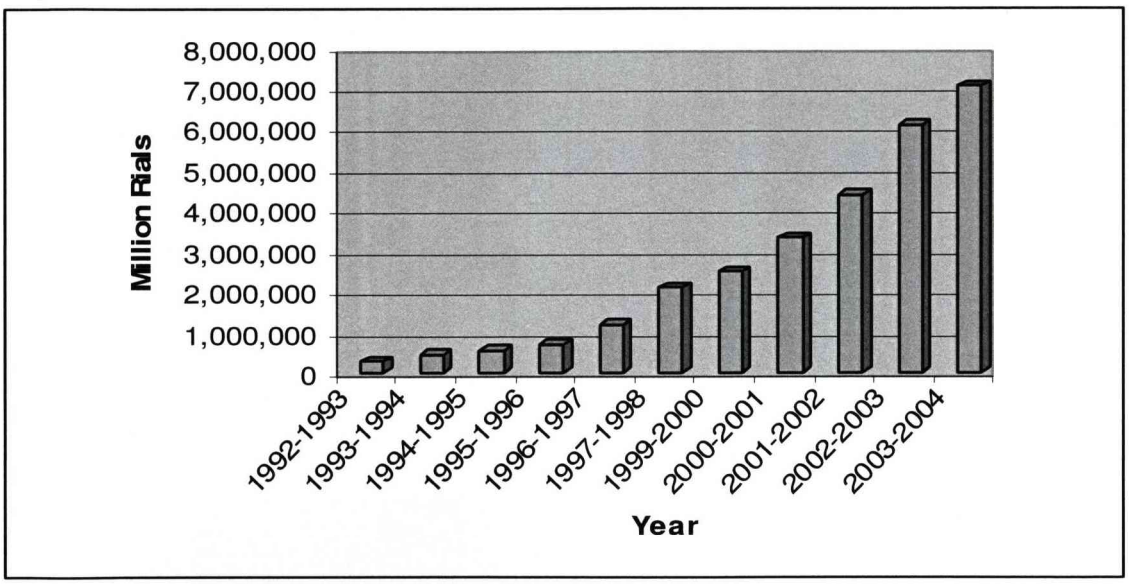
> *"Considering the members of High Insurance Council, it is clear the highest authorities of Health system, Managing and Planning Organisation, and Insurance Organisations are members of the Council. [After establishment of Ministry of Welfare and Social Security, the Minister of W&SS also added to the Council]. Per capita health expenditure must be suggested to the council by the Ministry of Health and M&PO. The council then is to decide the final amount and announce it to the cabinet for verification. The question is that while the council, after spending many hours on this matter and reached the consensus, announced the figure of 5,900 Toman as PCHE, now the cabinet decrease it to 3,890 Toman. It is not clear where this figure came from"* (Dr. 16).

The limitation of financial resources has limited both the quality and quantity of health insurance services for all beneficiary groups except governmental staff as the government is to provide health insurance for them. Financial issues are addressed in greater detail below.

Financial

Health expenditures of the Insurance Organisations have increased significantly in recent years with health expenditures of the Social Security Health Insurance organisation in 2003-2004 nearly 25 times greater than it was in 1992-1993 (Figure 5.3).

Figure 5.3 Therapeutic Expenditures of Social Security Insurance Organisation between 1992 and 2004*, **.



Data Source: Social Security Seasonal Letter (Faslnaameye Taa'min-e Ejtemaayee), various years

* Associated number of financial year 2001-2001 is estimated by the journal
** Associated number of 2001-2002 was not available

Many of interviewees perceived that an unrealistic determination of per head health expenditure is the main cause of the financial difficulties being experienced by HIOs. Dr 15 stated that the expectations of health insurance organisations were far in excess of their financial abilities.

> *"The main problem in health insurance organisations is the imbalance in relationship between their premium and the covered*

services. Thus the expectations from health insurance organisations are greater than their abilities. No insurance organisation is able to cover unlimited services, even the most powerful of them" (Dr. 16).

Dr. 9 supported this perception and explored how this limitation can affect health insurance activities.

"The actual per-head health expenditure of the population is much higher than the cabinet has determined. This is one of the main reasons for delay in reimbursement of hospitals and other medical services providers" (Dr. 9).

Dr Fazel, ex-minister of Culture and Higher Education, confirmed this difficulty and explained the implications of this issue.

"Delay and imperfect reimbursement of health insurance organisations to state hospitals has caused serious problems for them. They are not even able to pay their utility bills, much less buy new medical equipment" (Fazel).

Dr Abulhasani, Director of the Office of Policy and Monitoring of Medical Tariffs at Ministry of Health, believed that late reimbursements to healthcare providers causes major problems:

"Budget limitations of insurance organisations led to late payment to providers of healthcare services. Thus it is not surprising that many private health centres and hospitals do not accept some insured patients" (Dr Abulhasani).

Dr. 17 supported this idea and added that ultimately the government helps HIOs to pay off their debts to hospitals and other healthcare providers.

"Almost all of health insurance accounts in MSIO have had losses in their accounts. We have serious difficulties in reimbursement to

hospitals, physicians, clinical laboratories with our current budget. However, finally the government will help us to reimburse their money" (Dr. 17).

The method of premium setting has a direct impact on the financial resources available to the insurance organisations. In MSIO the premium of consumers is a fixed percent of PCHE, regardless of the individuals' socioeconomics class which Dr. 13 perceived to be an irrational basis for premium setting.

"One of our essential challenges is the premium of individuals is a fixed figure. It does not matter if the difference between the income of individuals is for example 5 times higher than the others. For example if PCHE is determined as 5,000 Tomans, all of governmental staffs must pay 1,500 Tomans every month. It doesn't matter if the person receive 1,000,000 Tomans per month or 200, 000 Tomans!" (Dr. 13)

Dr. 20 focused on how the system has difficulty in allocating subsidises between eligible individuals:

"We are distributing the governmental subsidise between all individuals equally. There is no strategic method for targeting vulnerable individuals. All individuals in one group receive the same amount of subsidise. Well the result is clear. Individuals who need it more may receive less than they need and the individuals who don't need it at all obtain it" (Dr. 20).

Many other factors contribute towards financial problems. Foremost amongst these factors is the uncontrolled utilisation of new and expensive health technologies within the health market of Iran. Many interviewees emphasised this point in their interviews. Dr. 18, for example said:

"New technologies are increasingly developing and being imported to Iran. New technologies and drugs need to pass some basic

criteria to be included in our policy. However, the important point is that after primary ratification, there is no systematic method of evaluation and guideline for utilization of new and high cost technologies" (Dr. 18).

Regarding the process of ratification of new drugs to be included in the service package of HIOs, Dr. 17 said:

"There are two different strategies for including new technologies in health insurance policies; one of them is for drugs and the other for medical devices and therapeutic methods. For pharmaceuticals, the first step is that the new drug must be added to Iranian Pharmacopeia before it could be considered by the High Insurance Committee (HIC). In fact the Food and Drug Department (FDD) of Iran evaluate the effectiveness of drugs. Medical devices and therapeutic methods, however, go directly to HIC to be included in health insurance policies. The HIC is responsible to evaluate whether HIOs are able to afford the extra cost of the new technology. If it is affordable for HIOs, the HIC approve the new technology to be covered in health policies, otherwise, it has to find the required resources for the new technology before adding it to health insurance services. All decisions of the HIC must be ratified by the cabinet to be carried out. This process may take two years!" (Dr. 17)

The Iranian FDD (Food & Drug Department) attempts to evaluate the effectiveness of drugs based on international studies that conform to American or European standards (See Chapter 6). Dr. 18 stated that internal committees prepare the relevant information for HIC to support their decision-making.

"Every individual, usually doctors, specialists, medical groups or Patients' Societies can suggest any drugs or medical devices to local or central department of health insurance. The individual can enclose any positive and supportive evidence/s confirming the

effectiveness of the drugs or devices. Then the relevant information regarding the numbers of patients and total cost of treatment will be collected by internal committees. All of this information then will be transferred to the High Insurance Committee for assessing affordability" (Dr. 18).

A further major problem is that the utilisation of new and expensive technologies is not subject to strong or effective monitoring. Dr. 17, believed that:

"The problems of new health technologies for HIOs start after approval of the new technologies. The case is that when a technology enters the insurance policies, both patients and doctors intend to use it, regardless of its specific medical indication. This is obvious that a CT scan is more precise than a simple radiography and also a MRI scan is even more accurate than a CT scanner. But the question is at what price?" (Dr. 17)

Whereas Dr. 17 attributed high utilization of technologies to better quality and effectiveness of new technologies, Dr. 19 believed that perverse financial incentives may exist for recommending new and expensive technologies. He focused on instrumental diagnostic technologies.

"It was obvious that establishment of new technologies, say CT scanner, increases the demand for them, but our evaluations shows that wherever the doctors had some contribution in investment for the instrument, the increase in utilisation of the technology were much higher than where the instrument was belong to a state hospital or therapeutic centre. These differences are sometimes 6-10 times higher!" (Dr. 19).

New technologies in Iran may not replace older ones, but may simply be added, particularly in the case of diagnostic technologies. Dr. 20 emphasised this problem:

> *"Our data shows that as MRI Scanner establishes in a city, utilization of them also increases. That is, instead of distribution of current patients within the available MRI centres, numbers patients who are sent to MRI centres increase. It is surprising that this is while the numbers of radiographies and CT scans also has not decreased! We have faced with the same problem in the case of Gamma Scanners and Angiographs"* (Dr. 20).

Another factor that encourages utilisation of new technologies is the health culture of the population. Dr. 17 pointed out this issue:

> *"One time I had a meeting with one of the specialists who prescribed considerable numbers of new and expensive drugs. In fact he prescribed usual and indigenous drugs (i.e. drugs manufactured in Iran) rarely. I asked him why he prescribed just expensive and foreign drugs. He said: the patient who comes to be visited by me, particularly from smaller cities, expected me to prescribe different from his or her previous doctors. If I prescribe the same drugs he or she may no longer comes to be visited by me!"* (Dr. 17)

Dr. 20 believed that the lack of any systematic control of the interface between primary and secondary care leads to inappropriate utilization of healthcare technologies which consequently increases expenditure:

> *"Our health system is not a well-defined system. From one side, doctors are free to prescribe whatever they think is right, and from the other side, patients are free to choose any doctor they wish based on their own criteria. For example they may choose a paediatrician or even a specific specialist for a common child's cold. What is more is that they may select a doctor, completely wrongly. Therefore for one medical problem, a patient may change 5 doctors before being visited by the right doctor! And each time he or she may receive a pharmaceutical prescription or clinical tests!"* (Dr. 20)

Dr. Moosavi, director of MSIO in 2004 focused on the need to develop the Family Doctor Scheme:

> *"In my opinion, we will witness further difficulties and problems in healthcare delivery services and health insurance system, unless we establish the Family Doctor and referral system in the country"* (Moosavi, 2004).

Health technology management, also, has direct impact on over utilisation of health technologies in Iran. The introduction of instrumental and diagnostic technologies in Iran is not based on the needs of the population as pointed out by Dr. 17:

> *"It is worth considering the method and the process of importing and distributing of instrumental technologies in healthcare services. It is surprising to see that sometimes the establishment of a new technology was simply because of political pressure. That is, from time to time you can see that a Member of Parliament supports the establishment of such technologies simply to attract more votes for the next election!"* (Dr. 17)

Ineffective monitoring of the healthcare market has increased utilisation of healthcare services and hence expenditures of health insurance organisations. Dr. 15 stated that:

> *"There are important concerns in monitoring the healthcare market. While we are paying for over utilization of healthcare services, there are serious debates regarding the acceptability and authority of the monitoring of health insurance organisations. The official health authorities as well as the Iranian Medical Society and the Iranian Pharmacist Society do not support the insurance organisations monitoring system strongly. They believe that the monitoring of the healthcare system is their duty and that health insurance*

organisations should not be involved in this job. However, we believe that they don't do their job effectively" (Dr. 15).

Understanding the reasons for such perverse incentives for over utilization of new technologies would help health policy makers to find a solution. These matters are discussed later in this chapter.

5.7.2.2 External factors

Pharmaceutical prices

New approaches to pharmaceutical regulations have significantly affected management and planning of health insurance organisations (see Chapter 6). The trends toward decreasing the subsidy provided to pharmaceutical industries and changing the basis for price setting of pharmaceutical products led to a sharp increase in health insurance expenditures as emphasised by Dr 19:

"Changing the price of pharmaceutical products every so often, has affected our financial system seriously. Our pharmaceutical expenditures have increased 23 percent in the first months of 2005-2006. However, this is partly because of price changes and partly as results of increase in usage of the pharmaceutical products" (Dr. 19).

Population and economy

Health insurance represents a risk sharing contract between the health insurance agency and the insured. The benefits of both insurers and customers will increase even further if the majority of customers are low risk clients (Jacobs and Rapoport 2004); (Walley, Haycox et al. 2004). However, it seems that young Iranian population do not perceive the importance of health insurance as emphasised by Dr. 12:

"The age structure of our population shows clearly that our population are young. The young population believe that they are healthy enough to not be covered by any health insurance agencies. So they try to escape from health insurance organisations. While the young population could be seen as long term investment and planning for insurance organisations, it does not have this function for our country at the moment" (Dr. 12).

Dr. 15 supported the problem of "escape" rate from health insurance:

"If young peoples join the insurance policy, they will pay 30 years premium. However the data show that people have 18.5 years premium payment in SSIO in average. This figure shows clearly that we have high rate of insurance escape in our country" (Dr. 15).

5.7.3 Potential solutions

Given the lack of any systematic and effective approach to the evaluation of new health technologies, provincial departments of HIOs have focused on trying to ensure the effective use of instrumental technologies. This is mainly because over utilization of instrumental and diagnostic technologies is so evident as to make it impossible to justify. Dr. 17 stated that:

"We have defined some standards for utilisation of some technologies and have been asking doctors and technicians to complete the forms and send a copy of them to us to be considered for reimbursement. For instance, for Echocardiography we have designed a form which is including some medical information such as level of hypertension, the status of the heart, and the main complaint of the patient. The other thing we have done is that we provide feed back to doctors that prescribe MRI and CT scan carelessly. For example we report to them that around 100 percent of the results of your requested MRIs have been normal! And if they don't care we consequently set a level of limitation for them for

recommending MRI scan. However, I should state that, firstly, theses activities are not very effective and systematic. Secondly they are not running nationally and this may cause some debates in itself" (Dr. 17).

The Minister of Welfare and Social Security emphasised the complex difficulties facing the Ministry. The Minister, Kazemi, stated that:

"Data collection is going very slowly! There are some unacceptable and strange feelings about releasing data. I have frequently heard that "this information is secret"! So it is not possible to collect all relevant information regarding vulnerable peoples very soon" (Kazemi).

Considerable numbers of interviewees believed that the structure of healthcare delivery system as a fundamental cause of the current challenges to the health insurance system and that reforms to the health system would reduce these challenges. Dr 19 stated that:

"The establishment of the Family Doctor Scheme is one of the urgent needs of the health system. It could correct our present patterns of healthcare utilization and could also reduce unnecessary usage of new and expensive technologies. We need to focus more on general practitioners" (Dr. 20).

The need for continuous training and effective monitoring were emphasised by Dr 16:

"I think many of the difficulties can be solved if we focus more on continuous training and effective monitoring. Training can reduce the medical incentives for prescribing just new medicines. Effective monitoring can reduce non medical reasons say, financial incentives, for over utilisation of medical services" (Dr. 17).

Almost all of the interviewees believed that increasing the level of financial resources made available to the insurance organisations would lead to improvements in both the quantity and quality of service delivery. Dr. 15 stated that:

> *"Per capita health expenditures must be determined realistically. Only in this condition we can set our services realistically and reimburse to healthcare providers without delay. This could obviously improve quality of healthcare services and then increase satisfaction of the patients from both health insurances and healthcare services"* (Dr. 15).

Dr. 10 supported this idea and stated that:

> *"My opinion is that every year, one figure is announced as per capita health expenditure that is not compatible with the reality of our society. Thus, it is obvious that this can cause some challenges between providers and consumers of the healthcare services and consequently could decrease the quantity and quality levels of the services to the society. I agree that watching and monitoring health cares are necessary, but the main challenge is that this credit is not enough"* (Dr. 10).

Dr. 18 criticized the method of including and rejecting selected healthcare services in insurance coverage. He said:

> *"The current method of including and rejecting healthcare services is not very good. Sometimes we accept cheaper services and reject their alternative services simply because our resources are limited. This is while the alternative service may provide better benefits for the patients. For example, tooth treatment and its filling up services are not including of our covered services, while we cover tooth pulling up services! Well, if the patient is young, it is obvious that treatment of his or her tooth provide better health for his or her future. However in many times, due to financial problem, patient*

may decide to take his/her tooth off rather than to treat it" (Dr. 18).

The main issues in the field of health insurance in Iran are summarised in Box 5.1.

Box 5.1 The Summary of health insurance issues in Iran

- Internal factors
  - Four main HIOs with different level of financial power
  - Uninsured population
  - The process and method of decision making
  - Limited financial resources
  - Uncontrolled utilization of new and high-cost technologies
  - Method of including or rejecting new health technologies

- External factors
  - Increasing pharmaceutical expenditures
  - Challenges of "*young*" population (high escape rate)
  - Structure of health care delivery system (lack of family doctors)

5.8 Analysis and Discussion

The results of the interviews emphasise that the health insurance system in Iran has developed greatly in terms of population coverage despite facing substantial challenges and difficulties in recent years.

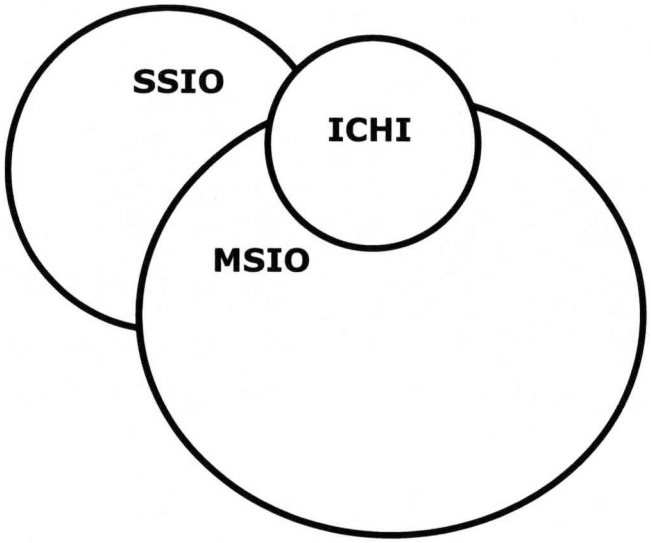
The theoretical concepts and practical issues underlying the health insurance market are well developed (Cutler and Zeckhauser 1999); (Folland, Goodman et al. 2003); (Jacobs and Rapoport 2004); (Walley, Haycox et al. 2004). As Box 5.1 emphasises, the interviewees discussed a wide range of challenges facing the health insurance system in Iran. One of the main challenges was the plethora of insurance organisations. Many

of the interviewees pointed out the problems inherent in coordinating the activities of four different health insurance organisations.

Article 29 of the Iranian Constitution emphasises the need to provide minimum standards of healthcare services available for all (Iranian Constitution, 1979). In addition, the provision of subsidies for disadvantaged and vulnerable people highlights the importance of providing equitable access to healthcare services. The Public Health Act emphasises the importance of protecting customers of insurance agencies against financial losses caused by unforeseen health problems. If these two objectives are shared by all health insurance organisations, then it would appear to be reasonable to conclude that all insurance companies share the same goals.

The next issue to examine is the extent to which the targeted population being served by the organisations are different. There appears to be significant similarities between the targeted populations of the organisations, particularly between ICHI customers and MSIO customers. According to the Rural Insurance Scheme, all villagers and citizens of small cities are to be covered by that scheme, however, most customers of the ICHI are from villages and small cities (Dr. 11). As such, it is clear that the residents of villages and small cities could be covered by both ICHI and MSIO. Although the targeted populations of the Health Insurance Organisations are different in theory, there appears to be a significant overlap between the targeted populations of the Organisations. Figure 5.4 shows a schematic distribution of the Iranian population between three main Health Insurance Organisations.

Figure 5.4 Probable distribution of the population between three Health Insurance Organisations



All health insurance organisations except SSIO are strongly dependent on the government for their financial resources. The levels of dependency of MSIO and ICHI on government subsidises are very high. This support is enhanced when the government reimburses the deficits of the MSIO at the end of its financial year.

Table 5.2 The contribution of the government in financial resources of Health Insurance Organisations

Health Insurance Organisation	Subsidies (General Budget)
SSIO	3 Percent of consumers' salary
MSIO	Up to 80 percent of PCHE
ICHI	80 Percent of the total budget

All of the Health Insurance Organisations have common goals, governmental common levels of support and strong correlation in their targeted populations. It seems therefore that the merging of these Organisations could improve the efficiency of the health insurance system in Iran through decreasing the administration costs of the health

insurance system (Folland, Goodman et al. 2003); (Jacobs and Rapoport 2004) and from savings related to a reduction in overlapping coverage.

Adverse selection results from asymmetric information about the health status of individuals who want to buy health insurance policy (Folland, Goodman et al. 2003); (Donaldson and Gerard 2004); (Jacobs and Rapoport 2004); (Walley, Haycox et al. 2004). The problem of adverse selection does not appear to be a significant problem in the Iranian health insurance market because firstly, the majority of the population are under compulsory health insurance schemes. In addition, considerable numbers of health insurance policies are offered with large public subsidies and the majority of the Iranian population are categorised in young age group, which normally equates with low risk.

The problem of moral hazard also affects the health insurance system in Iran (Cutler and Zeckhauser 1999); (Jacobs and Rapoport 2004); (Walley, Haycox et al. 2004). From the consumers' perspective, the existence of subsidies provides a clear incentive to over-demand. Specific Patients (SPs) receive their services and medicines mainly free of charge, however, they are monitored closely and hence the problem of moral hazard should be minimised.

The problem of moral hazard on the provider side ("Supplier-Induced Demand") ((Cutler and Zeckhauser 1999); (McGuire 2000); (Jacobs and Rapoport 2004); (Walley, Haycox et al. 2004) exists when the physician influences a patient's demand for care against the physician's interpretation of the best interest of the patient (McGuire 2000). The results of interviews emphasise that there are serious concerns about SID in Iran.

The process and the methods of decision making in health insurance system also need be considered. As some interviewees emphasised, the process of decision making about a new health technology, takes approximately 2 years. As also stated by the interviewees, the main criteria for adopting new technologies within the health insurance system

is usually affordability. That is, if the Health Insurance Organisation has enough money for the technology, the HIC accept it, otherwise it becomes the HIC's responsibility to review its required financial resources. However, before evaluating the affordability of the technology, the efficacy of the medicines must be approved by the Iranian FDD and the effectiveness of medical devices must be approved by professional bodies in the field.

As the interviewees stated, the basis for assessing the effectiveness of new devices or technologies is verification by professional international agencies, such as American Food and Drug Association (FDA), UK MHRA for drugs and i.e. American Heart Association (AHA) for devices. However it is important to note that none of these organisations evaluate effectiveness in clinical practice. In fact, Evidence Based Medicine (EBM) emerged in response to numbers of critiques on the effectiveness of medical devices and healthcare (Claridge and Fabian 2005). Therefore the HIC should give more consideration to Evidence Based Medicine and assessments of cost and clinical effectiveness, rather than just the availability of Market Licences.

The use of 'affordability' as the entire economic criterion for selecting or rejecting new medical technologies and therapeutic methods appears to be inappropriate (Feeny, Guyatt et al. 1986). It seems clear that focussing simply on affordability fails to identify and prioritise the efficiency of available healthcare services or technologies. Simply by applying the affordability method, decision makers will not able to identify relevant alternatives (Drummond, Sculpher et al. 2005). For example if a suggested health technology is to reduce morbidity due to chronic lung disease, then preventive programmes, for example cessation of cigarette smoking and car pollution reduction, may provide a more efficient way to achieve that objective. It seems therefore necessary for the HIC to undertake systematic effectiveness and economic evaluation methods for assessing new health devices and technologies.

Health technology assessment can help HIOs in several types of challenges and issues. The main aim of HTA is to promote more rational use of health technologies (Banta and Luce 1993). Economic evaluation of healthcare programmes, which assesses resource use (cost) of the alternatives together with their outcomes (benefits) (Feeny, Guyatt et al. 1986); (Drummond, Sculpher et al. 2005), can help HIOs and HIC to adopt new health technologies more effectively. The essential aim to systematic economic evaluation is to provide a clear structure for understanding decisions and their consequences in the field of healthcare services (Haycox, Boland et al. 2004) which will assist health insurance policy makers to allocate their limited resources more efficiently.

5.9 Conclusion

The coverage of the Iranian health insurance system has increased considerably in last three decades despite facing challenges in terms of efficiency, equity and effectiveness of its services. It seems clear that one of the key sources of inefficiency and inequity in health insurance system is the structural organisation of health insurance in Iran. This is highly important given the considerable numbers of Iranian population who live in relative or absolute poverty. The lack of HTA in assessing both costs and consequences of new technologies has generated a wide range of inefficiencies within the system.

CHAPTER 6

PHARMACEUTICALS IN IRAN

6 PHARMACEUTICALS IN IRAN

6.1 Introduction

Pharmaceuticals are important component of any Health Systems and throughout the world pharmaceutical expenditure has been growing rapidly (Danzon and Pauly 2002); (Walley, Haycox et al. 2004). Various explanations have been provided for this increase, including increasing insurance coverage (Danzon and Pauly 2002), increasing availability of pharmaceuticals, development of new medicines, and a demographic trend towards an aging population (Morris 2000). In addition to these general causes, there will also be specific causes underlying this increase in each country.

The aim of this chapter is to review the pharmaceutical market in Iran and evaluates its performance. Information about the history and structural organisation of pharmaceuticals was primarily drawn from a literature review with a range of issues being further explored in the interview analysis.

In order to identify relevant published materials about pharmaceutical system in Iran, the following search terms were utilised: Iran, Pharmaceutical market, pharmaceutical regulation, and pharmaceutical policy. Perhaps unsurprisingly, the results were extremely limited and hence the search of published materials was supplemented by search in local books and journals including, Razi, Darouva Darmaan (Drugs and Therapeutics) and Iranian Journal of Public Health.

The first part of the chapter describes Pharmaceutical organisation and regulation in Iran with the results of the interviews being discussed in the second part.

6.2 History of the pharmaceutical sector

6.2.1 Introduction

The Islamic revolution in 1979, development of Generic Scheme in 1981 and the eight-year war (1980-1988) all imposed significant influences on pharmaceutical regulation, policy and industry in Iran. To provide a clear framework for understanding the pharmaceutical policy and regulation in Iran, I have classified the history of modern pharmaceuticals in Iran into three main periods; Development & Imports, Domestic Production & Growth, and Improvement & Competition. Each of these is discussed in greater detail below.

6.2.2 Development & imports (1850-1980)

The first steps towards modern pharmaceutical production started around 1850 in the pharmaceutical laboratories of the Polytechnic College (Dar-ol-fonoon). The first School of Pharmacy was established at the University of Tehran in 1936, followed by Tabriz and Esfahan in 1949 and 1956 respectively (Montaseri 2000). Production of some simple dosage forms was under way by 1946, when the first modern pharmaceutical laboratory was established by Dr. Abidi. Tolidaru and Daropakhsh were the first two Iranian modern pharmaceutical factories that established in 1953 and 1963 respectively. The first monitoring law on the regulation of pharmaceuticals, foods and drinks was passed in 1955 (Lotfi 2000). In 1964 the government passed a law to support foreign investment in Iran which led to many international pharmaceutical companies locating in as cheap labour and access to large markets made such investment attractive for foreign pharmaceutical companies. 41 pharmaceutical factories were operating in Iran by 1979, most of which were branches of foreign companies (Dr. 22). In 1979, around 4,000 different Pharmaceutical products were available in Iran; 7% of which were imported by foreign companies and 30% were produced domestically – the majority under licence from foreign companies (Siamak-Nejad 1989). The lack of a national regulation or a systematic method for distributing

pharmaceutical products represented an essential challenge in this period (Vazari 1991).

6.2.3 Domestic production & growth (1980-1990)

In 1980, the Iranian National Industries Organisation nationalised multinational companies and transferred their ownerships to the organisation. The new owners of the companies sold their products through generic names only after this date.

Revolution and war led to a scarcity of medicines, particularly in the early years of the war (Dr. 23) which caused major problems for both patients and the government (Siamak-Nejad 1989). The Generic Scheme (1980) was designed to ensure that all of the pharmaceutical companies had to use the International Non-proprietary Names (INN) for their products. All general practitioners and specialists were asked to utilise generic names of drugs for their patients. Specific drugs that were not included in the national drug list could still prescribed by their trade names. Establishment of a drug-rationing system, supporting domestic companies to increase their production, and importing only essential drugs were the major pharmaceutical policies employed by the government to control drug use.

The main goals of the Generic Scheme were to promote domestic production of pharmaceuticals and to improve equality of access to good quality drugs at an appropriate price.

The Evaluation and Compilation Council of Pharmaceuticals is in charge of updating the Iranian drug list regularly. After implementation of the Generic Scheme only around 1,000 of the 4,000 previously available drugs in the market were approved for inclusion on the Iranian Drugs' List as the other drugs were considered me-too drugs or simply unnecessary.

Domestic production of generics reduced the price of drugs significantly. However, the onset of the war increased the demand for pharmaceuticals

dramatically which led to rapid growth in the production. Domestic companies produced only 15-30% of the pharmaceuticals used in Iran before 1980 but supplied more than 86% in 1988. Eight new pharmaceutical companies were established during this period (Dr. 22).

Expanding production was the first priority of the government in those years (Dr. 24). The government closely managed the pharmaceutical market with every activity in pharmaceutical factories required to get the agreement of the government (Dr. 22; Dr. 23; Dr. 25). Each factory received subsidised foreign currency to facilitate the importation of the drugs' ingredients, machinery parts, and other relevant materials in order to ensure the price of the medicines remained low and stable (Dr. 23).

A national distribution system was also established in which six companies delivered pharmaceuticals throughout the country which increased the availability of pharmaceuticals within Iran significantly (Montaseri 1986).

6.2.4 Improvement & competition (1990-present)

During this period, the pharmaceutical industry was faced with a range of challenges. From the consumers' side, the limited availability of certain drugs made the population unhappy with the pharmaceutical policy of the country. From the providers' side, the lack of market competition and immense bureaucracy reduced efficiency (Nik-Nejad 1992). This led to the initiation of market-oriented reforms in 1989 in which the pharmaceutical industries were transferred to private and semi-private ownership. As part of these reforms, the government reduced the subsidy provided to the factories and eased the regulation of imports (Dr. 22; Dr. 23). Factories could produce as much as they wished and were free to sell and export their products (Dr. 21).

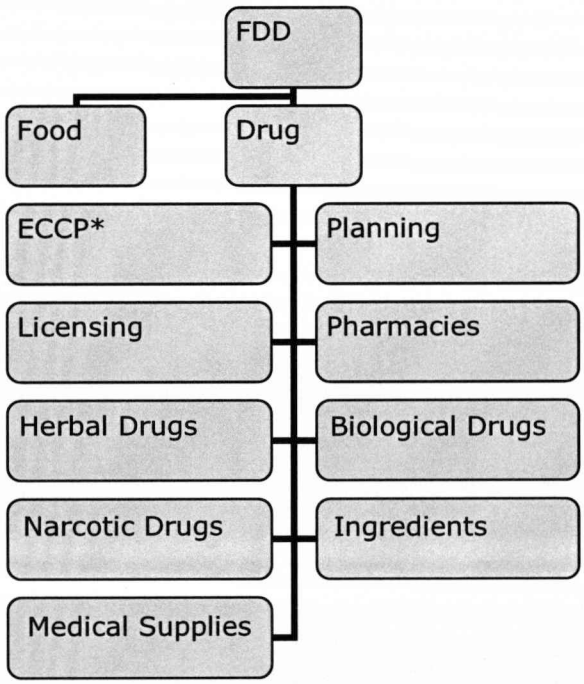
The trend during this period was toward the establishment of the pharmaceutical market, ending the rationing system, allowing easier access to foreign markets and ending the monopoly of importing drugs.

Irrespective of domestic production of specific drugs, importation of similar branded products was allowed at a fixed price.

6.3 Organisational structure of pharmaceutical system

As explained in Chapter 4, the Ministry of Health is made of five divisions, each headed by a deputy minister (Figure 4.11). The Deputy of Food and Drug (Food and Drug Department) is in charge of planning, controlling and monitoring all kind of pharmaceutical activities in Iran. Food and Drug Department (FDD) is constructed from 9 departments (Figure 6.1).

Figure 6.1 Structural Organisation of Food and Drug Department



* The Evaluation and Compilation Council of Pharmaceuticals

The Evaluation and Compilation Council of Pharmaceuticals was established in 1980 to plan and coordinate the implementation of the Scheme. The main duties of the Council were threefold:

- Determination of the type and the aspects of the required pharmaceuticals for the country using scientific literature and expert consultations based on:

    - Country's need
    - Effectiveness
    - Safety
    - Ease of usage
    - Ease of preparation
    - Ease of storage
    - Appropriate price

- Assessing suggestions or critiques about required pharmaceuticals and form opinions on:

    - Rejection of ineffective and less effective drugs, based on comparison with their alternatives
    - Adding new drugs to the Iranian Generic List of Drugs
    - Replacing drugs with better alternatives
    - Considering the drugs' feature such as formulation and dosage form

- Educating health workers and patients on the rational utilisation of drugs through drugs' information leaflets

The Council encompasses all pharmaceutical sections and has representatives from universities, pharmaceutical industries, pharmacies, drug importers and the society of pharmacists. The Planning department is responsible for:

    - Estimating annual drug needs and planning how this will be met by both domestic production and foreign import

- Providing statistics about production, import and distribution of drugs

The Licensing department issues production licences and undertakes quality control tests, bioavailability and bioequivalency tests.

The National Committee for Rational Prescribing and Utilisation of Drugs was established in 1996 to encourage the rational and scientific usage of drugs. Although the Committee is not officially placed of the FDD organisational chart, it had 39 branches in Medical Universities in Iran by 2003. The objectives of the Committee are as follows:

1. Improving the quality of healthcare services and preventing irrational utilisation of drugs
2. Assisting pharmaceutical and health planning
3. Generating data for educational purposes
4. Rational reduction in unnecessary pharmaceutical expenditures
5. Providing guideline for better prescribing and rational usage of drugs and healthcare services
6. Improving the health culture of the population; i.e. reducing high risk behaviours

The Committee uses the insurers' databases to select 100 prescriptions of each doctor for an evaluation which are then sent to doctors with a range of recommendations. The Committee has no legal power and thus, where important problems are found in a doctors' prescribing, the result will also be sent to the Medical Society of Iran for action. The Medical Society may issue an oral or written warning or, in some cases, withdraw the medical licence of the doctor.

6.4 Pharmaceutical system in practice (the results of the interviews)

6.4.1 Main achievements

The goal of securing equity in access to drugs has been an important goal in pharmaceutical policy. In this regard, the Generic Scheme (GS) is considered a great achievement. Dr. 23 explained that:

> *"The development of the Generic Scheme was a great improvement in pharmaceutical policy. What happened in Iran in the period of 1-2 years usually takes 5-10 years to be settled in other countries"* (Dr. 23).

The unique political and social situations within Iran were important factors underlying the rapid development of the Scheme. Dr. 26 focussed on the economic results of the GS:

> *"The Generic Scheme did not bring knowledge to us. It was not very attractive for doctors, either; because it reduced the range of alternatives in prescribing. But it was certainly the right decision in terms of economics. It reduced the price of pharmaceuticals 8 times"* (Dr. 26).

Dr. 27 emphasised the positive impact of the GS on the economics of the pharmaceuticals:

> *"In contrast to many criticisms of the GS, I believe that it was the right decision at the right time. Without the GS, it would have been more difficult to manage the need for drugs increased by the war. We needed a great amount of drugs with low price during the war"* (Dr. 27)

The WHO also considered the GS in Iran to be an extremely well-constructed and unique scheme (Montaseri 1986). The development of

domestic pharmaceutical industries was also considered to be an important achievement by the interviewees. Dr 20 described this improvement:

> *"The share of domestic production from pharmaceutical market before the GS was between 20-30 percent. But this amount has increased to around 95 percent. If you consider the growth of the pharmaceutical market and the population, you can see that our pharmaceutical production has increased extremely well"* (Dr. 22).

Table 6.1 supports this view and shows that in 2005 nearly 96% of pharmaceutical market in volume terms was from domestic products, however, imported drugs took up 24.8% of the pharmaceutical market by value.

Increasing the availability of pharmaceuticals at identical price nationally was considered to be an important achievement of the GS. Dr 26 emphasised this achievement:

> *"Distribution of the pharmaceuticals was previously mainly based on the results of the companies' visitors' activities. It is obvious that they spent their time in the larger cities. The availability of drugs for small cities and villages were not good at all. The establishment of a distribution network was therefore an essential step forward in improvement of drugs' availability at identical price over the country. Through this system, every single pharmacy, even the furthest from Tehran, is served the same way as the capital pharmacies"* (Dr. 28).

Irrespective of considerable achievements of the pharmaceutical system in recent decades, the system is now subject to substantial challenges and difficulties. These challenges are discussed in the following part.

6.4.2 Current challenges and difficulties

The challenges and difficulties currently facing the industry are analysed below in terms of Pharmaceutical Expenditures, Pharmaceutical Industry, and Planning & Management.

6.4.2.1 Pharmaceutical expenditures

Pharmaceutical expenditures have increased sharply in recent years (Table 6.1) with Figure 6.2 emphasising that it has nearly tripled in the past five years. One of the main reasons underlying this increase is higher utilisation of new and high cost technologies. Dr. 28 pointed out this issue and explained:

> *"Incredible speed in the development of new technologies and the knowledge of Iranian doctors about these technologies has increased demand for consumption of these high cost technologies sharply"* (Dr. 28)

Increasing expectations of the population represent a crucial factor underpinning increased demand for new and high cost technologies.

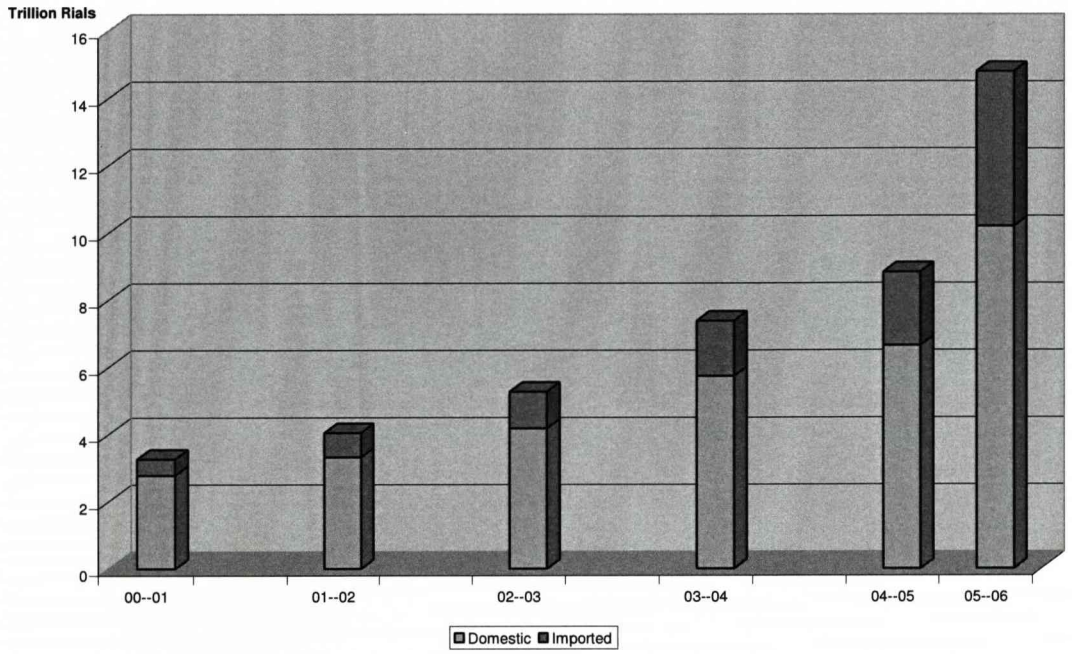
> *"The expectations of the population and even health workers are increased exceptionally in recent years. These expectations are much greater than the ability of the government to meet them. While the per capita health expenditures of the population is around 5-6 US Dollar, the population expected to receive the services like Switzerland with 20-30 times greater per capita health expenditures!"* (Dr. 29)

Table 6.1 The volume and the cost of pharmaceuticals in Iran between 2000 and 2006

	00--01	01--02	02--03	03--04	04--05	05--06
Cost						
Domestic	2,782,311,807,592	3,323,765,559,771	4,183,095,286,917	5,737,747,407,932	6,637,235,793,997	10,180,938,126,559
Imported	484,205,846,425	719,605,604,881	1,085,363,567,433	1,638,773,896,544	2,188,247,253,855	4,606,860,316,989
Total	3,266,517,654,017	4,043,371,164,652	5,268,458,854,350	7,376,521,304,476	8,825,483,047,852	14,787,798,443,539
Volume						
Domestic	17,929,424,921	18,978,955,007	19,549,097,387	21,678,809,865	22,110,972,532	26,572,978,681
Imported	697,918,749	784,112,750	784,112,750	915,066,600	943,421,642	1,158,555,635
Total	18,627,343,670	19,763,067,757	20,333,210,137	22,593,876,465	23,054,394,174	27,731,534,316
Percentage of volume of the imported pharmaceuticals	3.7	4.0	3.9	4.1	4.1	4.2
Percentage of costs of the imported pharmaceuticals	15	18	21	22	25	31

Data Source: Iranian Statistics Letter, various years

Figure 6.2 Pharmaceutical expenditure in Iran, 2000 - 2006



Data Source: Iranian Statistics Letter, various years

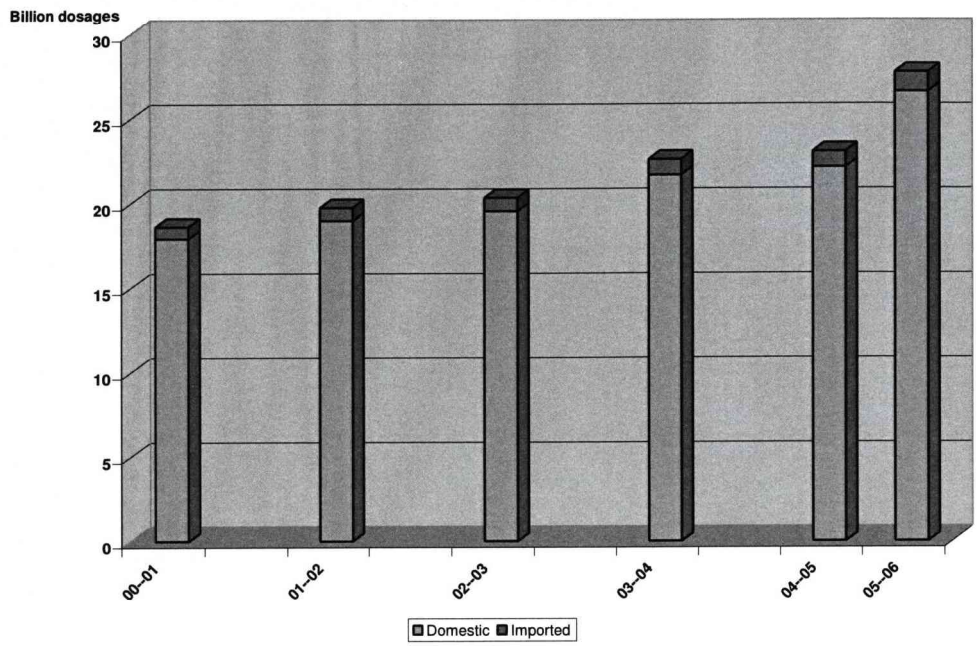
6.4.2.2 Price rises

A policy of decreasing subsidies to the pharmaceutical factories was applied from 2001. Dr. Cheraghali, the Acting Deputy of Ministry of Health in Food and Drug in 2003, explained why this was the case:

> *"The FDD carried out a study to find the cause or causes of the shortage and limitation of drugs in the market. There were 13 causes for the problem. However, we realised that the key cause of the problem was the dependency of the pharmaceutical factories on financial support of the government. So we tried to make the factories free from this limitation factor. This policy came to practice from 2001".*

As a result of this policy, the price of pharmaceuticals increased and pharmaceutical expenditures rose significantly.

Figure 6.3 The distribution of pharmaceutical volume between 2000 and 2006 based on domestic and imported share of the market



Data Source: Iranian Statistics Letter, various years

6.4.2.3 The lack of therapeutic guidelines

Irrational consumption of drugs in Iran is considered to be one of the main causes of increased pharmaceutical expenditures in Iran. Dr. 30 explained this problem.

> *"Irrational consumption and irrational prescribing are both important difficulties of the utilization of pharmaceuticals in Iran. The average number of drugs in prescription in Iran is more than 3 at the present time (2003). Although it has improved significantly from the time it was between 4 and 5 in 1998, but still is higher that the suggested number of the WHO which is 1.5 and is even higher than the average number of drugs per prescription in Asian countries which is 2.4"* (Dr. 30).

Dr. Ahmadiyani, the Deputy Minister of Health in Food and Drug Department, stated that the utilisation of anti infectious products in Iran is very high.

> *"It is right that per capita usage of drugs were increased from 265 numbers in 1997 to 340 numbers in 2003. But we believe that this is mainly because of improvement in availability, rather than irrational utilisation of drugs. Overuse and misuse of antibiotics are two important problems in our current system. Antibiotic resistance is frequently happening in both outpatient and inpatient cases"* (Ahmadiyani).

A study of drug utilisation in Iran confirmed that approximately 60% of patients received antimicrobial drugs in their prescriptions (Soleimani, F. 2003). Replacing cheap old drugs with expensive new ones also causes increasing expenditure. Dr. 30 explained this matter.

> *"One of the important factors that have resulted to the increase in the pharmaceutical expenditures is the prescribing pattern of the doctors. For example, until two years ago, doctors prescribe Amoxcycilin for treatment of Sinusitis, but they are currently prescribe Co-Amoxyclave"* (Dr. 30).

Dr. 31 attributed such problems to the lack of therapeutic guidelines and stated that:

> *"As there are no therapeutic guidelines in our health system, the doctors prescribe new and expensive drugs freely. Prescribing some brand name drugs will pave the way for importing new drugs without a comprehensive assessment. It will be more difficult to stop such prescribing without clear and effective therapeutic guidelines"* (Dr. 31).

Dr. 28 explained how the medical sector puts pressures on the pharmaceutical system.

> *"The medical sector put pressure on the pharmaceutical system strongly. There is no therapeutic guideline, neither in governmental section nor in Non Governmental Organisations (NGO) like Medical Society of Iran. The doctors are free to prescribe whatever they like. When a doctor prescribes a drug which is not in the Iranian Drug List, the drug might be not available in pharmaceutical market. But the patient comes here [to the FDD building] and requests the drug from us. This is the first and the most important point of the pressure"* (Dr. 28).

Inappropriate patterns of prescribing have also increased adverse reactions so that over 8% of inpatient admissions to hospital are now due to adverse reactions (Gholami, Parsa et al. 2005).

6.4.2.4 Healthcare system

The structure healthcare delivery encourages overuse of pharmaceuticals and therefore increased pharmaceutical expenditures. Dr. 30 pointed out this issue.

> *"The frequency of patients visiting doctors is also very important in utilisation of the Pharmaceuticals. And if you note that the patients expect to receive prescription with drugs at every visit, it would be clear that utilisation of drugs would increase considerably"* (Dr. 30).

Dr. 23 emphasised that a primary reason for visiting various doctors is to meet the patients' expectation for a prescription. He stated:

> *"Considerable numbers of the population expect their doctors to prescribe medicines. And if one doctor does not follow the patients' expectation, the patient may go to visit another doctor"* (Dr. 23).

6.4.2.5 Pharmacies

The low profit rate for pharmacies can enhance the over-utilisation of pharmaceuticals. Dr. 32 explained this matter:

> *"A pharmacy is in fact an economic firm. The lack of sufficient consideration to the pharmacy's income is encouraged the pharmacists to ignore the regulation of Over-The-Counter (OTC) and Prescription-Only- Drug (POD). So they may sell the requested drugs from patients to increase their income"* (Dr. 32).

Dr. 33 viewed the problem of Pharmacies' income from another point of view. He stated that:

> *"There are many uncertainties in the pharmacy about what drugs will be required that encourage pharmacists to have a large stock. Furthermore, health insurance organisations usually are late in their reimbursement. It is therefore clear that a pharmacy needs a huge amount of investment. In addition, the running cost of pharmacies, comparing with other healthcare services, is high. These elements encourage the pharmacists to sell more drugs to achieve a reasonable profit"* (Dr. 33).

The increased prevalence of over-the-counter medicines is also an element increasing pharmaceutical expenditure:

> *"The low price drug was obviously one of the causes of self-treatment. That is, because the price of drugs were low, even in full payment, some patients were encouraged to buy it directly from pharmacies rather than to pay for doctor's visit and buy their medicines with a prescription"* (Dr. 24).

6.4.2.6 Smuggling

The increase in smuggling of cheap drugs to neighbouring countries resulted from the subsidies provided to the pharmaceutical factories.

> *"Considerable amounts of drugs were smuggled, and still are, to Afghanistan, Iraq, Azerbaijan, and even Pakistan. This is because the difference between the price of the drugs in Iran and these countries are very high"* (Dr. 22).

Dr. 33 emphasised the problem of smuggling and added that over 3 million tablets were smuggled in the first 5 months of 2004. The governments' abolition of subsidies to pharmaceutical factories should reduce this problem.

6.4.3 The Iranian pharmaceutical industry

6.4.3.1 Introduction

The domestic pharmaceutical industry in Iran has made an important contribution to pharmaceutical and healthcare policy in Iran, particularly after the development of the Generic Scheme (GS) in 1980.

6.4.3.2 Pricing

Pharmaceutical pricing was one of the most controversial issues arising from the interviews. This method of pricing is currently based on the cost of the ingredients, plus various additional costs incurred by the pharmaceutical factories (Producers & Consumers Supporting Organisations, 1990). The profit levels agreed for the factories in 2005 was 15% of the final cost (Dr. 22). Dr Ahmadiyani, Deputy Minister of Health in Food and Drug in 1997-1999 and 2001-2004, explained the reasons behind his policy to reduce subsidies to pharmaceutical factories.

> *"Some of financial related elements that affected availability of pharmaceuticals in Iran were included the lack of on-time allocating*

of the resources to the pharmaceutical sector, and some difficulties in cooperation between the Iranian Central Bank and some International Banks. But these causes were in fact the results of another main cause. The main cause of the problem was the dependency of the pharmaceutical sector on the government budget. So we decided to reduce this dependency and make the industry free" (Ahmadiyani).

Every interviewee felt that the availability of drugs increased in response to this new policy:

"The financial freedom of pharmaceutical factories from the state's budget has increased the production of the factories and, in consequence, improved the availability of the drugs for the population" (Dr. 28).

There still exist rigorous regulations constraining the pricing of pharmaceutical products which was criticised by many interviewees:

"The prices of the products are not market price. The government has set a low marginal profit for the factories so that they are not able to renew their instrumental machines or spend much on Research and Development (R&D). We have asked the government to acknowledge our R&D expenditures, but it has been unsuccessful so far" (Dr. 23).

Dr. 27 supported this challenge and explained why there is insufficient investment in research and development:

"One of the fields where we are largely behind multinational companies is the field of research on new drugs and technologies. There are several reasons that could explain this. But from the pharmaceutical industries' point of view, one of the important explanations is that the Ministry of Economics, which has one member in the Pharmaceutical Pricing Committee, does not

consider research expenditures or at best consider it inappropriately. Thus a pharmaceutical factory may prefer to not invest in these fields. In fact the Ministry of Health does not pay for production technology" (Dr. 27).

Dr. 22 stated that Iran should move away from a government controlled pricing system:

"There is a law that stated that if any industry or company does not receive financial support from the government, it is free to set the price of its products or services itself based on the market price. But, when we refer to this law, the FDD responses are that the pharmaceuticals are exceptions. This is because the pharmaceutical are part of strategic productions. That is they are very important" (Dr. 22).

Dr. 21 emphasised the need for price control in Iran:

"The main reason for setting the pharmaceutical price is because the affordability of the drugs to the population is important to us".

Dr. 31 criticised this idea:

"There are controversial perspectives on pharmaceuticals. From one hand the pharmaceuticals are a strategic commodity in the country and therefore their price should be kept low and affordable for all. But, from the other hand, the profit of companies and individuals that are working on such a strategic commodity are not considered reasonably" (Dr. 31).

Dr. 26 critiqued the need for rigorous regulation of pharmaceutical prices:

"The detailed regulation of the government on pricing pharmaceuticals sometimes has stopped a production line in domestic factories. And then the government had to import the

same drug at a price of 6-7 times greater than the suggested price" (Dr. 26).

Dr. 23 explained that the main reason for resisting the market price for pharmaceutical is that the government itself is the main insurer organisation.

"The government is itself an insurer organisation. The level of coverage has increased. At present more than 70 percent of the population have insurance policy. Thus this is clear that the government is against the price rising" (Dr. 23).

Dr. 31 believed that the rate of pharmaceutical price increasing still exceeded the general inflation rate:

"It is important to note that in contrast to replacing the subsidy US dollar (equal to 175 Toman) to free market US dollar (equal to 800 Toman), 4.6 times greater, the pharmaceutical prices increased only 10 percent! And this means there is unbalance between investment in the pharmaceutical sector and the other industrial sectors in the country" (Dr. 31).

Dr. 34 emphasised the importance of the political make-up of the committee:

"The power of the representatives of the Ministry of Health in the Pharmaceutical Pricing Committee is less than the representatives of the other organisation, or at least is not strong enough. This is while the representatives of the Providers and Consumers Supporting Organisation have the right of the veto!" (Dr. 34).

Dr. 22 confirmed this imbalance of power:

"Last year the FDD wanted to increase the price of pharmaceuticals around 10 percent. The Producer Consumer Supporting

Organisation (PCSO) was against that decision. Finally, in contrast to the opinion of the PCSO, the Ministry of Health increased the price. However the PCSO challenged the Ministry on legal ground and dragged the Ministry authorities to the court!" (Dr. 22).

It is clear that many efforts have been made to support the pharmaceutical industry in Iran (Montaseri 2000). Montaseri however stated that such supportive policies increased the dependency of the pharmaceutical factories on such financial support. Introducing a free and competitive market, therefore, should reform and improve the GS. Dr 21 stated that the new policy is to determine a ceiling price rather than an actual price:

"The pricing system is the other factor that has changed in this period. According to the new policy, the pricing committee will determine the ceiling price. Pharmaceutical factories are free to set their products' price equal to or less than the specified price. This may open a competition among factories" (Cheraghali).

Dr. 29 believed that the new policy may lead to improving the quality of pharmaceuticals:

"I think the way out of the problem is to consider different price for different quality. The quality of the pharmaceutical factories is not the same, why should their price be the same? We have to find some ways to encourage better products" (Dr. 29).

This policy added another difficulty to the domestic pharmaceutical industry:

"It is necessary to encourage a competitive market in pharmaceutical market. This could increase positive competition. But the intervention of the government in the market has caused negative competition. That is, when the FDD announces a specific price for a specific drug, the pharmaceutical factories may try to

reduce their production costs to increase their profit. This may impact on the quality of their products negatively" (Dr. 34).

Dr. 22 supported this idea and explained that the pharmaceutical market in Iran is now faced with the problem of excess-capacity.

"The excess-capacity of the production is also a serious difficulty. In the past, only 2 companies produced Co-Trimaxazole Tablet, but they are now 7; only 3 factories produced Acetaminophen Drop, they are now 10, and so on. This excess-capacity has developed internal competition. However, in this competition the companies with lower production costs have higher manoeuvre power. This is while, for increasing the quality of the products you usually need to spend money on it" (Dr. 22).

The price of pharmaceuticals has a crucial role in helping pharmaceutical policy-makers to achieve their objectives. This is discussed in further detail later in this chapter.

6.4.3.3 Administration process

The interviewees perceived that delays in decision-making imposed considerable costs on pharmaceutical factories. Dr. 23 explained that.

"The process of the pricing system, irrespective of its nature, is the other difficulty that the pharmaceutical factories are faced with. For example there was a technical problem in our Multi Vitamin Drop, we discussed it with FDD and announced to them that we want to improve our production line. We also submitted our documents for increasing the price of the new shape drug. We worked on the production line for three years to improve the quality of the drop. It is now 4 months that the product is ready to distribute, but we are still waiting for the price!" (Dr. 23).

Dr. 22 pointed out the process of ingredient ratification:

> *"If we want to replace the source of our ingredients, we have to announce it to the FDD and get its ratification. This process usually takes around 6 months!"* (Dr. 22).

Dr. 31 complained about delays in the administration process:

> *"Every single change in the price of pharmaceuticals must be approved by senior authorities through a long administrative process. Furthermore the organisational structure of FDD has not improved very much. Sometimes an administration work that should be done in a 3-4 days may take even months. This may take away some of our opportunities"* (Dr. 31).

6.4.3.4 Other difficulties

A range of other difficulties were addressed by interviewees. Shortage of skills was one element which presented difficulties for the pharmaceutical industries:

> *"Professional skills are different from professional knowledge. By professional skill I mean industrial skills, i.e. methods of increasing production efficiency. There are some complex pharmaceutical machines that we may don't use to 100 percent of their capacities. This is what we need to focus on it and invest on it appropriately"* (Dr. 29).

Political and economic instabilities also imposed important problems on the pharmaceutical industry:

> *"Our ingredient stock is normally higher than standard rate. In fact we have to keep it high to ensure we have sufficient materials to run our production line. This is because of the unstable status of our political and economic conditions"* (Dr 20).

Electronic connection to the international banking system could facilitate financial relationship more easily.

> *"Our financial relationships with international companies are still mainly paper based. And because all of international banks are now shifted to electronic based banking, we have some difficulties to link these two different systems together. Many times we have to pay more to do these jobs"* (Dr 20).

6.4.3.5 Health insurance

Dr. 21 explained why health insurance organisations are against the new policy of the FDD.

> *"We are increasingly under pressures from Health Insurance Organisation. They believe that the policy of price rationalization in the pharmaceutical market has increased their expenditures significantly and therefore they are against this policy"* (Dr. 21).

The FDD felt that the best way of supporting the population against the high expenditures of the pharmaceuticals was through health insurance organisations (Ahmadiyani).

> *"The FDD believes that any subsidies must be paid to the end users, which are patients. The best method of doing this is through health insurance. We had a successful experience in Human Menopausal Gonadotropin (HMG) vials. When we stopped paying a subsidy and the price increased to market price, the consumption of the drug decreased significantly. We then tried to reimburse the true users of the drug through health insurance organisations"* (Dr. 21).

Dr. 28 supported this idea and added:

> *"Regarding the good coverage of the health insurance within the population, the best way of supporting the population is through health insurer organisations. This could increase the financial power of the insurers to cover unsubsidised drugs"* (Dr. 28).

However, the main problem still remained unsolved. Dr.35 believed the health insurance organisations are not able to afford high cost drugs.

> *"The issue of drug shortage is now ended. However, the problem now is that the high cost of the new drugs, which are mainly imported drugs. The cost of new drugs is so high and is almost unaffordable for both the population and the insurer organisations"* (Dr.35).

6.4.4 Planning and management

Issues relating to planning and management of pharmaceuticals received considerable attention from the interviewees:

> *"Many of our present challenges are rooted in management and policies. Thus I believe the management has the highest role in the pharmaceutical System. The problem is that we do not look at the Management from professional and academic point of views. Furthermore, unstable management is also a very important problem that has imposed considerable costs on our system"* (Dr.35).

Dr. 21 pointed out the importance of having a clear National Health Policy.

> *"It is necessary for the Ministry of Health to provide a comprehensive National Health Policy. Without such a document we are not able to plan for the future precisely and in a coherent and consistent manner with other departments"* (Dr. 21).

The need for comprehensive and detailed plans is supported by Dr 34:

> *"We need, firstly, to provide a National Health Policy; and then define our National Pharmaceutical Policy within that policy. It is important to provide clear answers for some important questions; i.e. whether the import of drugs is entirely free; whether pharmaceutical factories can produce under-licence drugs; what the policy of the government about the foreign products is; whether the government wishes to support domestic factories"* (Dr. 34).

Dr. 23 felt that the lack of comprehensive future plan has made the FDD act passively:

> *"Our pharmaceutical system is operating passively. That is, there is not still a comprehensive and detailed plan in the Health System and its components. Or at best we do not feel that such a plan existed. It is still not clear what quality is acceptable for our system; it is not clear which group of the population the system wants to support in healthcare expenditures"* (Dr 21).

Dr. 31 pointed out that without precise definition of the tasks of the FDD it is difficult to state clearly whether objectives are being achieved.

> *"We need to define clearly what the pharmaceutical management means in the pharmaceutical system. If it means preparing the most cost-effective drugs for the population, we do not have it"* (Dr. 31).

However, it is very difficult to plan for the future without clear information on future policy.

> *"One of the important difficulties of the present situation of pharmaceutical industries is that with the development of the Generic Scheme, our communication with national pharmaceutical*

industry and international companies was cut. Although this relationship is now being restarted, we still do not know exactly what might be happening on next month! We are not able to assess the future policy of the government exactly and therefore it is very hard for us to provide a long term plan" (Dr. 26).

Planning and management is a key issue for improving the availability and the quality of Pharmaceutical services to the population with many current problems being attributable to perceived problems in pharmaceutical management.

6.4.5 Current controversies

The new approach of policy makers in the pharmaceutical system was perceived as being population-based rather than industry-based. This approach, however, has raised a range of issues about the policy and its potential results:

"The status of our pharmaceutical system is very similar to the pharmaceutical systems in capitalist countries. The FDD policy is not to support strongly the domestic pharmaceutical factories, like other industries. Therefore, it is predictable that in near future some of the factories that are not able to keep their share of the market merge with other factories. The production of drugs is now based on supply and demand. However, our system is still highly regulated. For example because the affordability to the population is very important, the FDD is determining the price of the pharmaceuticals" (Dr. 21).

Regarding the importation policy of the FDD, he explained:

"Although the import of foreign and brand name drugs are free, it is still necessary for importer/s to register their drugs before the importation. In addition a specific price scheme is applicable to them. According to the scheme, a tariff of 3-4 percent will be added

to those drugs where there is no domestic manufactured similar drug. For those which have a similar dosage form produced in Iran, a tariff up to 100 percent will be added to support domestic products" (Dr. 21).

The negative and positive impacts of these policies were explained as follows:

"There are two negative impacts of this new policy. First, this policy will increase the volume of pharmaceutical market. And secondly, this will increase the pressures on the insurer organisations to include brand name drugs in their policies. However, the policy has also two positive impacts. First, this policy will increase the pharmaceutical factories' competition which we believe will improve the domestic pharmaceutical industry as well as the quality of domestic products. Improving the availability of the drugs for the population will be the second positive result of this policy" (Dr. 21).

In contrast, Dr. 23 believed that the new policy of the FDD on importing the foreign drugs has increased pressures on domestic firms:

"The import of foreign drugs is now almost free for any type of the drugs, it doesn't matter if the drug is a tablet of Vitamin C or an anti-cancer vial. This may increase the frequency and availability of drugs, but it also could affect domestic firms adversely" (Dr. 23).

He explained how this affected the domestic factories:

"The representations of foreign companies can freely visit the doctors, particularly specialists, to encourage them to prescribe their brand drugs. So, first of all doctors prescribe the branded drugs, rather than generic ones. Secondly, even if the prescription is generic, pharmacies ask patients whether they want branded and foreign drugs or domestic drugs. This is because the brand name drugs are sometimes 20 times greater than generic name and then

the pharmacy can gain more profit in selling brand name drugs. So we can simply sell our drugs to people who are not able to afford brand name drugs!" (Dr. 23).

Dr. 31 emphasised the problems associated with imported drugs and added:

"The brand name drugs and complementary drugs are imported and smuggled into the country easily. Even newspapers advertise some of them. In pharmacies they are selling freely and have many customers. Many of the imported drugs are not new and high technology drugs, but still are more expensive than domestic drugs. For example, the Advil tablets (400 mg) is selling at 2500 Rials each, whereas the generic name tablets of Ibuprofen (400 mg) is only 110 Rials [22.7 times cheaper]" (Dr. 31).

Dr. 30 believed that these new policies will make the challenges faced by the pharmaceutical system even more complex.

"Free importation of new drugs is a wrong policy. This is because our domestic factories are not able to produce these new drugs independently, the majority of our population are not able to buy it, and the insurance organisations are not able to cover it! This simply will make the present challenges of the system more complex" (Dr. 30).

Dr. 28 believed that this policy is the result of pressures on the FDD:

"Increasing the pressure for new drugs and technologies from both the population and the doctors made the FDD reduce the regulation on importation of the foreign drugs. This is while the domestic factories have faced with lots of competition challenges between themselves" (Dr. 28).

Dr.35 pointed out the results of new policy on social justice:

> *"The social justice, particularly in health, is a common value in our country. But the reality is the wealthier people are benefiting from high quality services and the poorer have to accept the minimum standard services. The issue is that the gap between the wealthier and the poorer is going to be deeper and deeper"* (Dr.35).

Dr. 24 supported this opinion and focussed on the implications for the poor within Iran:

> *"The privatisation of pharmaceutical factories, the reduction of the government involvement in execution works, and pricing the pharmaceuticals at their true market price is necessary for improving the quality and the quantity of the domestic pharmaceutical products. But thinking about the population, particularly the poor and disadvantaged people, is also a crucial point to be considered"* (Dr. 24).

Dr. Ahmadiyani, explained his perception of the root of the pharmaceutical challenges and outlined his solution:

> *"It is important to note that the government is itself the biggest customer of the drugs. That is, around 35 percent of the drugs is bought directly by the Ministry of Health, through Medical Universities over the country. More than 50 percent of the prescription within the Medical Services Insurance Organisations (MSIO) is also paid by the government. That means the government is the customer for more than 75 percent of pharmaceutical products...It is also obvious that it is very hard for the government to afford such a huge amount of drugs. There are two ways out; first, strengthening the government financially, second, think whether this is a right policy for the government to pay such a huge amount? The first way is not a logical manner. How we can strengthen the government? Until when we can do*

that? The government has a limited budget. Thus this is not a good manner. I think the government should not be so involved in such matters at the earlier time; for example state health centres and hospital pharmacies: I think they should not be in the hand of the government" (Ahmadiyani).

In response to criticisms of his policy, he responded:

"I think every body must choose between the following two options: First, we have a limited budget for pharmaceuticals. We can provide specific number of pharmaceuticals for all, through insurance system and financial support. No drug should be permitted to be distributed outside of the system; because some people may able to afford it and some may not, and this could increase the gap between social classes.

Second, we have a limited budget and the government is not able to allocate sufficient resources to provide cheap drug for all [through subsidy]. The government has to do whatever it can, and let the others [private sector] do the part that the government is not able to do. The government is not responsible for the population whether they can afford it or not or they may afford it with difficulty.

I am in favour of the latter opinion and I am doing this way" (Ahmadiyani).

This opinion emphasises clearly the philosophy of his new pharmaceutical policy which is discussed in the following section.

Box 6.1 The summarised challenges facing the pharmaceutical industry

- Increasing expectations of both health workers and the population for receiving new pharmaceuticals
- Method of pricing pharmaceuticals
- High expenditures on new and expensive pharmaceutical products
- Overuse and misuse of the pharmaceuticals
- Limited funding for accessing to new drugs
- The lack of therapeutic guidelines
- Limited funding for R&D in pharmaceutical industry
- The lack of clear and detailed National Health Policy
- The lack of clear and detailed National Drug Policy

6.5 Analysis and discussion

The interviewees highlighted a range of challenges facing the pharmaceutical industry in Iran (Box 6.1) including the challenges and difficulties originating from the lack of clinical guidelines and the challenges derived from an ambiguous national drug policy.

The GS improved accessibility to pharmaceuticals through enhanced national distribution and decreased the price of pharmaceuticals significantly. However, challenges remained including dependency on government subsidies, lack of effective market competition, limited availability of drugs and low profit margins within the industry (Vazari 1991); (Heidar-Nejad 1992). Such challenges led to privatisation of the industry and enhanced freedom for importing foreign pharmaceuticals, however, the interviewees emphasised that the pharmaceutical system in Iran still faces a range of challenges.

Pharmaceutical pricing is controversial worldwide and many countries control the price of pharmaceutical products through various methods. The pricing system in Iran is largely based on "Cost Plus" in which prices are linked to the costs of manufacturing. Considerable numbers of the interviewees criticised this method of pricing for two reasons. Firstly, the FDD in Iran does not accept R&D expenditures as an integral element of manufacturing cost. This could adversely affect the ability of the Iranian industry to compete with multinational pharmaceutical companies in a relatively free market. Without sufficient investment, the domestic pharmaceutical industry will find it difficult to compete internationally. Though the privatisation of the industry in the 1990s and the controversial elimination of the subsidies and financial supports from the government in the early 2000s were two necessary steps towards the establishment of an independent pharmaceutical industry, without an effective pricing system the objectives of privatization may not be achieved as the pharmaceutical industry must invest in R&D to keep their share of the pharmaceutical market in the future.

This method of pricing may also adversely affect the quality of domestic pharmaceutical products. The industry might be encouraged to reduce its production expenditures to increase its profit by buying cheaper ingredients which may lead to lower quality of the products as Generic Scheme pharmacies are allowed to dispense the generic drugs from any factory they can source.

An undue concentration on pharmaceutical pricing may increase dependency of the domestic pharmaceutical market on international pharmaceutical companies. Such changes may increase pharmaceutical expenditures in Iran over the long term and reverse recent improvements in the domestic pharmaceutical industry. Table 6.1 and Figure 6.2 emphasised that imported drugs absorbed considerable financial resources while the volume of imported drugs increased from 3.7% in 2000 to just 4.2% in 2006, its share of financial expenditures increased from 15% to 31% over this period (Table 6.1). This may also reduce accessibility of imported expensive drugs to the Iranian population.

The current pricing system, particularly for imported drugs, emphasises that the FDD is still looking for ways to support the domestic pharmaceutical industry. But, the FDD needs a clear, accurate and comprehensive policy to achieve the optimum trade-off between protecting and supporting the Iranian pharmaceutical industry and providing optimal access to affordable pharmaceuticals for the Iranian population.

Many interviewees emphasised the paucity of therapeutic guidelines as a key issue in increasing pharmaceutical expenditure through increased adverse reactions and the redundant or ineffective usage of the pharmaceuticals. A high number of items per prescriptions is normal in Iran and a high rate of adverse drug reactions (Gholami, Parsa et al. 2005) provide clear evidence of the impact of the lack of therapeutic guidelines on health expenditures. The development of such therapeutic guidelines based on both clinical and cost-effectiveness studies offer the potential to enhance control of pharmaceutical expenditures and improve the quality of healthcare services in Iran. HTA can help promote more rational use of health technologies (Battista 2006) by enabling the health service to target on effective and cost-effective pharmaceuticals.

What is clear from the interviewees' and senior pharmaceutical policy makers' point of views is that a clear, comprehensive and acceptable set of goals and objectives for health and pharmaceutical policy still does not exist in Iran. The publication of Iran National Drug Policy in 2004, however ((F.D.D) 2004) provided a set of goals for the pharmaceutical system in Iran.

> *"Considering the raising of the pharmaceutical expenditures around the world as well as in Iran, the Ministry of Health and Medical Education must do act so the Health System is able to provide the most cost-effective drugs"* ((F.D.D) 2004).

The establishment of a clear National Health Policy would enable detailed consideration of the extent to which the established objectives are coherent.

6.6 Conclusion

Optimising structures of pharmaceutical regulation and policy is inherently complex and multifactoral (Mossialos, Mrazek et al. 2004). However, it has been compounded by a range of specific events which have increased complexity in Iran. Reforming the pricing system, implementing a HTA programme and optimising the balance between supporting pharmaceutical industry and ensuring availability of affordable pharmaceuticals for the population are of key importance in improving the pharmaceutical system in Iran.

CHAPTER 7

HEALTH TECHNOLOGY ASSESSMENT IN ENGLAND AND WALES AND ITS APPLICABILITY TO IRAN

7 HEALTH TECHNOLOGY ASSESSMENT IN ENGLAND AND WALES AND ITS APPLICABILITY TO IRAN

7.1 Introduction

This chapter reviews the health technology assessment (HTA) system in England and Wales (E&W) and discusses options available for optimising the use of health care technology in Iran. The advantage and disadvantage of various policy options are discussed and recommendations are made with regard to developing a technology assessment programme in Iran. This chapter aims to undertake the third step in Needs Assessment analysis; identifying possible solutions for the problems identified (Rouda and Kusy 1995). Particular attention is paid to the different context and requirements between a potential HTA system in Iran with what is currently operating within England and Wales (E&W). This is a method for comparative research where contextual interrogation precedes any analysis of similarity and difference (Iversen 1991). With the help of Comparative Contextual Analysis, similarities and differences between the Iranian and England and Wales (E&W) Health System are identified in this chapter. The results of the chapters 4-6 are used as the data for this analysis. As discussed in Chapter 2, HTA has developed from single technology assessment to service delivery assessment and prioritisation of the healthcare system (Banta and Behney 1981[a)]; (Banta and Luce 1993); (Battista 2006) . This growing breadth draws HTA closer to the political environment in which decisions are made and, as such, the adaptation of the HTA system to its political and cultural context becomes more important (Battista 2006).

In order to identify relevant and appropriate materials regarding the HTA system in E&W the websites of HTA Programme and National Institute for Health and Clinical Excellence (NICE) were used, together with electronic databases such as MEDLINE, EMBASE and Google Scholar. Key search terms such as 'NICE'; 'England'; 'Wales' and 'HTA Programme' were used to narrow down the range of the literature to more specific and relevant.

In this chapter the terms 'HTA', 'HTA programme' and 'HTA system' have been used frequently. It is therefore helpful to describe each term clearly to prevent further confusion. The term "health technology assessment" (HTA) alone carries the *scientific concept* of the HTA. The term "HTA programme" stands for the *organisational programme* based on the Research and Development department of the NHS. As the *assessment* procedure and the *appraisal* process are working in their specific ways, the term "HTA system" is used to include both the assessment and the appraisal process together.

7.2 Overview of health system in the UK

The National Health Service (NHS) was set up in 1948 to provide healthcare for all citizens, based on need rather than the ability to pay. One of the assumptions behind the establishment of the NHS was that much of the existing ill-health of the population occurred as a consequence of restricted access to healthcare by economically disadvantaged members of the population. The NHS therefore has always placed great value on equality of access with persons normally resident in the United Kingdom being eligible for services from the NHS (NHS 2006).

It was assumed that, once improved access to healthcare reduced this existing stock of ill-health, demand would fall to a lower long-term equilibrium level. Unfortunately, cultural, demographic and economic changes have led to a continuous expansion in demand, imposing extreme pressure on the philosophy underpinning the NHS. To confront such pressures, a major restructuring was undertaken in 1974 which introduced a new centralized system consisting of fourteen Regional Health Authorities (RHAs) supported by ninety Area Health Authorities. Perhaps the most fundamental reform to the structure of the NHS occurred in 1991 with the introduction of 'market' principles through the creation of an 'internal' market aimed at separating responsibility for identifying local care needs (purchasing) from the provision of care to meet those needs

(provision). The aim of this reform was to overcome the 'agency' relationship which had previously existed in the NHS which made clinicians responsible both for the identification of care needs and for the provision of services to meet those needs. By separating out the purchasing function it was felt that local purchasing agencies would be able to better identify the health needs of their local populations and to 'shop around' between competing purchasers to identify the provider who provides the greatest value for money in meeting those care needs. The introduction of such 'market pressures' was held to increase provider efficiency and transfer effective power from suppliers of care (hospitals) to the newly created purchasers. The election of a Labour Government in 1997 led to a new set of priorities which replaced the internal market with a system that placed far more emphasis on planning, collaboration and partnership-working. The re-election of Labour for a second term in 2001 introduced yet a further set of priorities (Stevens and Milne 2004). From 1999, the responsibility of healthcare in Scotland, Wales and Northern Ireland transferred to the Scottish Parliament, the Welsh Assembly, and the Northern Ireland Assembly, respectively (Davies 2006).

According to the health services scope and population coverage, the NHS is categorized as a "comprehensive health system" (Roemer 1991) and is recognized as one of the best health services in the world by the World Health Organization (W.H.O. 2000). However there need to be improvements to cope with the demands of the 21st century. The overall objectives of the NHS in 1948 were to meet all need for advice, treatment, and care ((MoH) 1944). However, the Royal Commission on the National Health Services found these original objectives unachievable and modified them to providing a broad range of services of a high standard, responsive to local needs, satisfying "reasonable expectations" of its users (H.M.S.O 1979).

7.2.1 Organizational structure of HTA in the UK

The structure of the UK health system underwent major organizational change following the election of the Labour Government in 1997. Their

plans for the NHS were set out originally in a White Paper entitled "The new NHS: modern, dependable" ((DoH) 1997) which entailed two major changes. The first focus was on dismantling the internal market in order to raise standards and enhance collaboration in the NHS ((DoH) 1997).

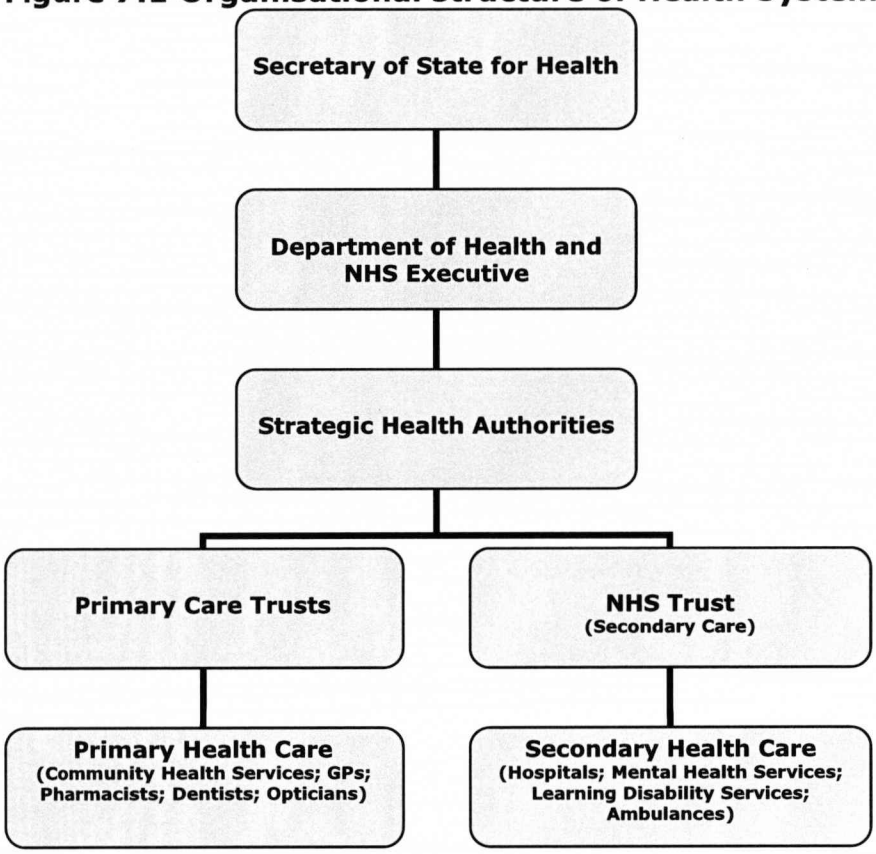
The second fundamental change was decentralization of power so that services would be sought from a much more diverse range of providers including private hospitals and foreign providers. The aim was for a more diverse service in which service provision became more patient-driven, less monopolistic, more diverse and exhibited greater plurality, and local ownership.

The Department of Health (DoH) is responsible for carrying out the policies of the government and communicating the strategic direction of the NHS, ensuring that money is spent and monitoring the standard and safety of services.

Primary care trusts (PCTs) run primary and community services and cimmission secondary care. PCTs are responsible for over 85% of NHS expenditure ((DoH) 2006).

England is now split into 10 Strategic Health Authorities (SHAs) set up in 2002 to monitor and improve health services in their local area. Within each SHA, the NHS is split into various types of Trusts that take responsibility for running NHS services in each area. The different Trust types are Acute Trusts, Ambulance Trusts, Care Trusts, Mental Health Trusts, Primary Care Trusts (PCTs) (NHS 2006). Figure 7.1 provides details of the organizational structure of the NHS.

Figure 7.1 Organisational structure of Health System in the UK



7.2.2 Healthcare delivery system in the UK

7.2.2.1 Primary healthcare services

Family doctors or community nurses are usually the first point of contact for patients when they need health advice or treatment. Around 90% of patient contacts occur in primary care leading to over 300 million consultations every year (Davies 2006). Primary care professionals are also the gatekeepers for specialist care within the NHS. This GP 'gate-keeping' role is an important element of the NHS as, unlike Iran, NHS patients do not have direct access to specialists.

7.2.2.2 Secondary healthcare services

NHS hospital services are run and managed by Acute Trusts, which make sure that hospitals provide high quality health care, and that they spend their money efficiently. They also decide on a strategy for how the hospital will develop, so that services improve.

7.2.3 Financing of the NHS

The system of health finance in the United Kingdom is less complex than in most other countries as the NHS is funded by the taxpayer and it is the responsibility of the Department of Health to provide health services to the general public through the NHS ((DoH) 2006). The centralized financing of the NHS ensures universal access to services regardless of ability to pay (Donaldson and Gerard 2004); (Davies 2006) as the consumer is able to access health services at zero price at the point of delivery (Davies 2006).

In 2005/06, over 94% of NHS funding came from general taxation and national insurance contributions. The NHS currently charges for prescriptions, dental treatments, sight tests, glasses and contact lenses, however, over 50% of prescriptions are free, together with widespread exemptions from charges for children under the age of 16, elderly people, those on low incomes and people with chronic conditions (Davies 2006).

Table 7.1 summarises the similarities and differences between the Iranian and UK health systems.

Table 7.1 Similarities and differences of health systems in Iran and England & Wales

Health System Elements	England & Wales	Iran
Health Policy	Centralized National Health Policy	Centralized National Health Policy
Primary Healthcare Services	Family Doctors	Patient Choose (Free access)
Secondary Healthcare Services	Referral System	Patient Choose (Direct access)
Method of Financing	General Taxation, Central	Mixed (Mainly Insurance based and Central co-payment)
Healthcare Management	Various levels; (Local Health Authorities and Trusts)	Various Levels; (Provincial Medical Universities)
Health Insurance	Within the NHS	Various types of Health Insurance Organisations
Insured population	99% (almost all)	Around 75% (estimation)
Patient-Doctor financial relationship	No (free at the point of delivery)	Yes (full price for uninsured, contribution for insured)

7.3 The development of HTA system in England and Wales

It is important to note that there is a clear distinction between *Assessment* and *Appraisal* in the process of HTA in the E&W. While health technology assessment is the analytical process of gathering and summarizing information about health technologies, technology appraisal is about the judgemental process of making a decision about health technologies. Health technology assessment is defined as

> *"...structured analysis of a health care technology, a set of related technologies, or a technology-related issue performed for the purpose of providing input to a policy decision"* ((O.T.A) 1994).

The HTA system started in the early 1990s with integration of economic evaluation, evidence-based healthcare and health technology assessment (Selley, Donovan et al. 1997). A parliamentary report on Priorities in Medical Research revealed a considerable gap between basic research and applied research and represented an important stimulus to the development of an HTA system in the UK. A new post of Director of Research and Development was created followed by "Assessing the Effects of Health Technologies ..." which led to the development of the HTA Programme in 1993.

The creation of an internal market created a formal set of authorities with responsibility for value for money (Milne and Hicks 1996) which played a crucial role in the development of HTA policy in the UK (Stevens and Milne 2004).

7.3.1 Health Technology Assessment

Many University-based research groups undertake health technology assessment together with considerable research and development groups within the NHS and pharmaceutical industries. Clinical trials and other primary research consume almost 90% of the programme budget (Stevens and Milne 2004). Stevens summarized the characteristics of the various products of HTA in Table 7.2.

Table 7.2 Collection and evaluation of evidence

	Topic Selection	Research Type	Customer	Analysis	Researcher	Time Line	Evaluation Assessment
Researcher-curiosity reports	Researcher driven	Primary usually	Not defined	Normally effectiveness only	Any bidder	Open/ Negotiated	Peer review
HTA main R&D program	Needs criteria	Secondary or primary	The NHS	Cost-effectiveness (cost-utility sometimes)	Any bidder	2-4 years	Peer review
HTA-NICE	NICE program	Secondary	NICE	Cost-utility Normally	6 ready team	6mths-1 year	Peer and industry review NICE Appraisal

Source: (Stevens and Milne 2004)

In 1993 the Health Technology Assessment programme was set up to undertake and fund high quality research on the costs, effectiveness and

broader impact of health technologies. The HTA is a national programme, dedicated to evaluation, which responds to the information needs of people who use, manage and provide care in the NHS. The programme is funded from the National Health Service Research and Development Section, and works alongside the Service Delivery and Organisation (SDO) and New and Emerging Applications of Technology (NEAT) Programmes.

The National Coordinating Centre for HTA (NCCHTA) coordinates the HTA programme on behalf of the Department of Health's Research and Development Division and manages and develops the HTA Programme. It also continually reviews the programme to make the process of needs-led health technology assessment more effective and efficient.

Structures of HTA throughout the world are changing and evolving at a rapid rate. As such, any description of such structures will almost inevitably become out of date very quickly. This dynamic nature of HTA is perhaps most obvious in the manner in which structures of HTA have expanded and altered in the UK. As such, I am aware that much of the material presented in this section is in danger of being overtaken by this rapid process of change and I caution readers to check the relevant HTA and NICE material for more recent material.

7.3.1.1 The process of HTA

NCCHTA identifies topics from NHS policy makers, managers, practitioners and service users and receives around 1000 topic suggestions every year (Walley 2007). Suggested topics are assessed by four HTA advisory panels: Diagnostic Technologies and Screening; Pharmaceuticals; Therapeutic Procedures and Disease Prevention. Following each panel meeting, researchers at the NCCHTA will prepare a short document, usually 3-4 pages, summarising the importance of a health problem, the current evidence base and cost of the intervention. These vignettes are made available to panel members to help them in their decision-making by highlighting issues that are important to patients or people using the services. Around 55 of the panel's finalised topics will be examined by the

HTA Prioritization Strategy Group (PSG) who assess the scientific, clinical and policy work lying behind the topics. The prioritized topics will then be referred to the HTA Programme to undertake a detailed clinical and economic evaluation.

The HTA Prioritization Strategy Group (PSG) is responsible for the oversight and approval of all topics recommended for research by the panels. The PSG is headed by the HTA Programme Director and include the four panel Chairs, the Chair of the Commissioning Board and the Executive Director of NCCHTA. The programme then issues Calls for Proposals and commissions research to answer the research questions.

The HTA Commissioning Board (HTACB) is in charge of allocating research topics to research groups who wish to undertake research in any particular area. The Board also ensures that research is well-designed, capable of being competently executed, uses cost effective protocols, and answers identified research needs. Several hundred expert peer reviewers assist the HTACB in undertaking these tasks.

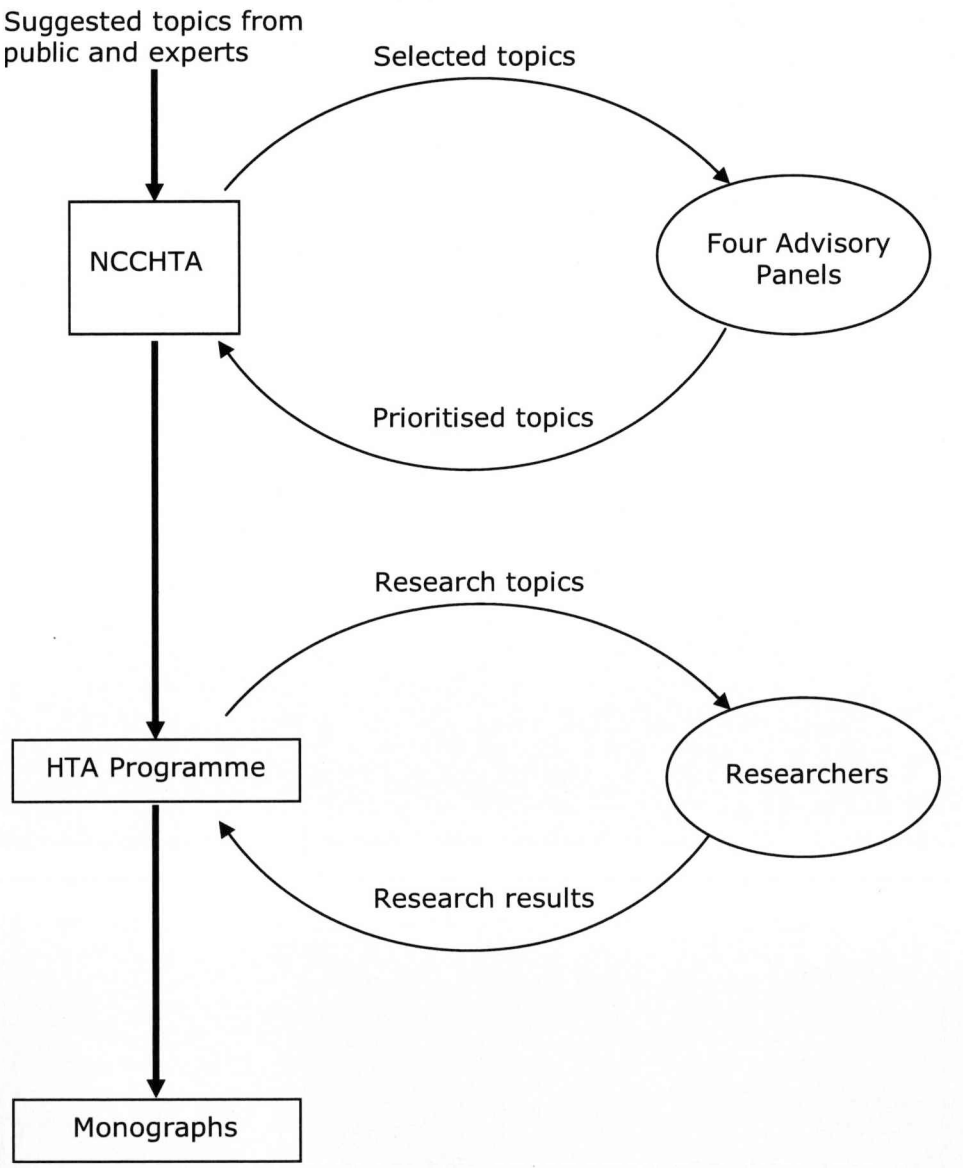
HTACB follows a number of principles in its processes. Firstly, it emphasises the quality of applicants and commissioned work as well as selection of highly respected referees as being very important elements. Secondly, openness and transparency of decision-making is crucial. Research topics are advertised openly and widely with all applicants being equally treated. Achieving its objectives efficiently is also crucial, which means using limited research resources to generate evidence of the greatest value given national priorities in health.

The HTA programme also has responsibility for commissioning the seven TARs teams on behalf of the NICE. TAR groups are based at the Universities of Aberdeen, Birmingham, Exeter, Liverpool, Sheffield, Southampton and York. They are Methodology Expert groups that work on NICE research topics but are free to bid for other research topics advertised by the HTA programme.

7.3.1.2 Publication and communication

The HTA Programme's communications strategy aims to ensure that the information generated by the research programme is easily accessible to a varied audience. Over 200 monographs from the programme have currently been published, with a further 50 reports anticipated each year. Publication in other peer-reviewed journals is also expected from all HTA projects.

Figure 7.1 Health Technology Assessment process in England and Wales



7.3.2 Health Technology Appraisal

7.3.2.1 Development of National Institute for Clinical Excellence (NICE)

Before the establishment of NICE in 1999, health technology appraisal was largely undertaken locally in response to the needs of local formularies and various health authorities and health organizations. The establishment of NICE brought health technology appraisal under one umbrella in England and Wales.

NICE was established to maximise the health gain from NHS resources, to address geographical inequities in the availability of technologies and minimise the possibility of further inequities, e.g 'postcode prescribing'. NICE offers health professionals in England and Wales advice on providing NHS patients with the highest attainable standards of care (NICE 2005) and provides guidance to the NHS on the use of new and established health technologies. NICE guidance is based upon an appraisal process that seeks and considers evidence derived from an independent assessment and from information provided by a variety of consultees.

The main aim of the NICE is to help decision-makers to focus their limited healthcare resources on the most clinically and cost-effective interventions and produce clear national guidance for the NHS by evaluating the clinical and cost-effectiveness of treatments and care for patients. To achieve this objective, NICE applies a system of technology appraisal, produce guideline, appraise safety and efficacy of new interventional procedures, and to do some ad hoc projects, say publishing Principles for the Best Practice in Clinical Audit (NICE 2006). NICE uses the results of the assessment side of HTA system and examine them with its own values and preferences (Stevens and Milne 2004)). Since its establishment as a Special Health Authority in 1999, NICE has significantly contributed to the promotion of evidence-based medicine and the cost-effective use of NHS resources and has produced 261 guidance documents on a wide range of Health Technologies (NICE 2007). Again, however, as with HTA in

general, it is important to acknowledge the dynamic nature in which structures and processes are evolving within NICE. Again, I caution the reader to update the material presented her in line with more recently presented material.

7.3.2.2 Process of technology appraisal in NICE

The first step in the technology appraisal process is the selection of a technology for appraisal. The Department of Health (DoH) and the National Assembly for Wales (NAW) are responsible for this step. The Department of Health (DoH) produces a list of provisional appraisal topics and NICE reviews the appropriateness of each of the suggestions. The suggestions are then filtered according to a checklist based on DoH selection criteria, developed in July 2006. The selection criteria take into account: burden of disease (population affected, morbidity, mortality), resource impact (i.e. the cost impact on the NHS or the public sector), policy importance (i.e. whether the topic falls within a government priority area), whether there is inappropriate variation in practice across the country and factors affecting the timeliness or urgency for guidance to be produced.

The topics may include all types of health technologies including emerging technologies, new technologies, and existing technologies (Stevens and Milne 2004). Identification of emerging technologies is undertaken by the National Horizon Scanning Centre at the University of Birmingham.

The suggestions are then reviewed by consideration panels composed of experts in the topic area, health service professionals and patient and carer representatives. The recommendations of the Panel go to the Department of Health and the Health Minister makes the final decision on which topics are referred to NICE for producing guidance.

NICE then invites stakeholder organisations to register their interest in individual guidance. The HTA programme commissions an independent academic centre, on behalf of NICE, to review published evidence on the

technology and prepare an assessment report. After receiving the results of the review, consultees and commentators are invited to comment on the report. NICE technology appraisal recommendations are prepared by an independent committee called the Technology Appraisal Committee. Committee members are appointed for a three-year term, and are drawn from the NHS, patient and carer organisations, academia and pharmaceutical and medical devices industries. Although the Technology Appraisal Committee seeks the views of organisations representing health professionals, patients, carers, manufacturers and the government, its advice is independent of any vested interests.

The National Collaborating Centre (NCC) determines the boundaries of the guideline. The guideline boundaries are then compiled in a Scoping document. The Scoping document delineates clearly what the guideline will and will not cover and the questions that will need to be asked. NICE, registered stakeholders and an independent Guideline Review Panel can all contribute to the development of the Scoping document. The NCC then establishes a Guideline Development Group made up of health professionals, representatives of patient and carer groups and technical experts. This group assesses the evidence available on the guideline topic and makes recommendations. Theses outcomes form the core of the draft guideline.

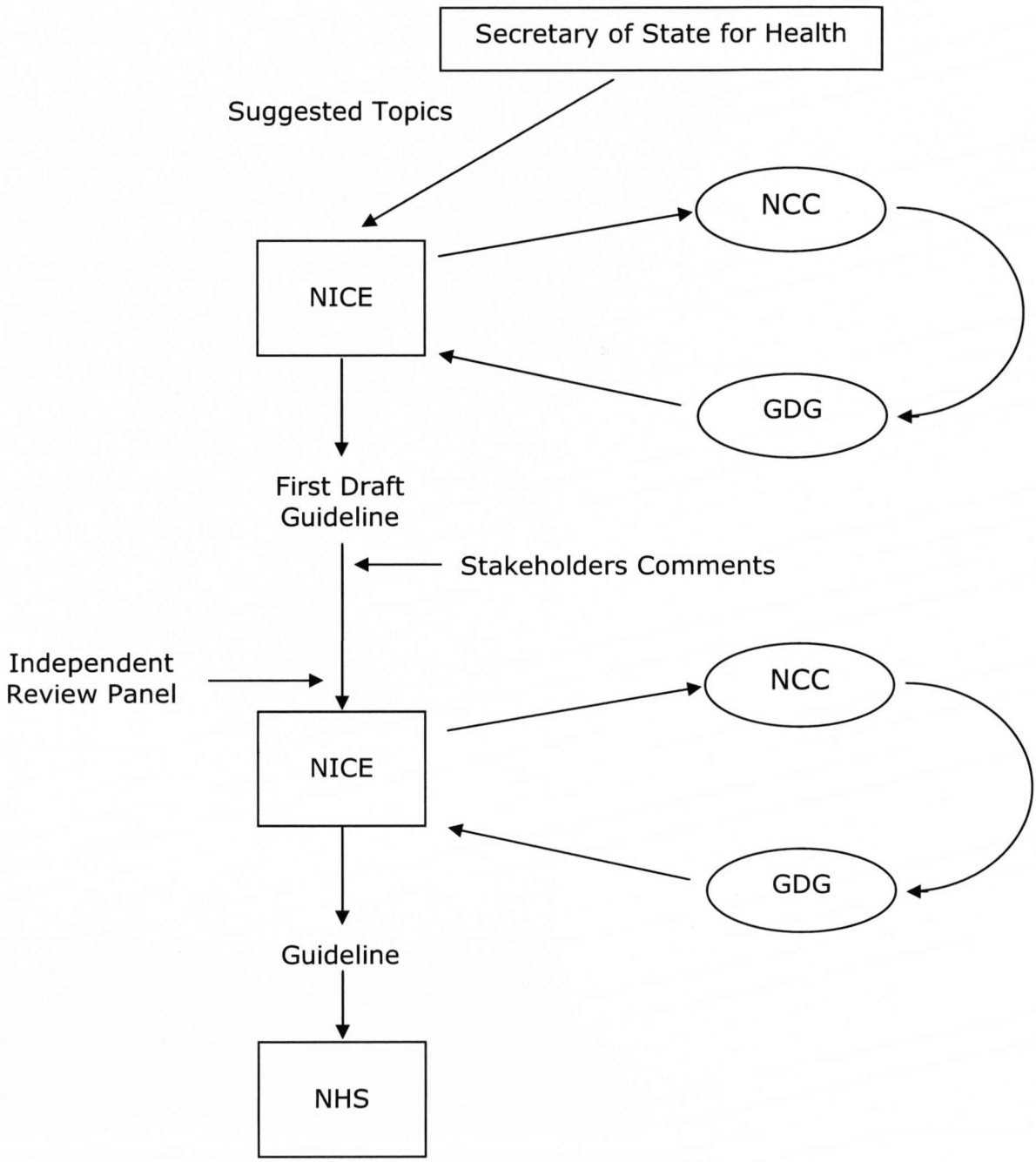
There are two consultation periods during which registered stakeholders comment on the draft guideline. The draft guideline is also posted on the NICE website during this period. An independent Guideline Review Panel (GRP) reviews the guideline and checks that stakeholders' comments have been taken into account. Following the second consultation period, the Guideline Development Group (GDG) finalises the recommendations and the NCC produces the final documents called Final Appraisal Determination (FAD). It submits FAD to NICE for approval. Consultees and stakeholders can appeal against the FAD. If there are no appeals, NICE formally approves the guideline and issues its guidance to the NHS.

The implementation of guidance is compulsory. The NHS is given three months to provide appropriate resources for the implementation of a NICE Guidance. The implementation of Guidelines in Clinical Practice and Public Health Guidelines are not compulsory.
summarizes the NICE appraisal process.

7.3.2.3 Single technology appraisal process

NICE is also trying to introduce a new, rapid process for assessing drugs and other treatments. The Single Technology Appraisal (STA) process is designed to produce guidance more quickly on life-saving drugs that have already been licensed. If the DoH approves the NICE application, NICE will issue a Guidance shortly after a drug becomes available for use in the NHS.

Figure 7.2 Summary of the NICE appraisal process



7.4 Discussion and overview of the HTA system in England and Wales

The HTA system in the England and Wales is an example of one of the pioneering HTA systems in the world. It has engaged actively with various

research centres and groups through the country and is well accepted within the NHS and by healthcare managers and policy makers.

Since its inception, the HTA system has raised many academic debates and challenges as to its methodology and process (Cookson, McDaid et al. 2001); (Maynard, Bloor et al. 2004); (Williams and Cookson 2006). Many of the critiques have targeted the scientific basis of the economic evaluation process (Sculpher, Drummond et al. 2001); (Birch and Gafni 2002); (Gafni and Birch 2003).

Sculpher believes that the evidence on which cost-benefit analysis is based is often incomplete or inappropriate. For example, the appraisal of hip prostheses suffered from the dearth of long-term data on revision rates (Sculpher, Drummond et al. 2001). The robustness of available clinical effectiveness data is also questionable. Approximately 67% of 326 economic evaluations in Australia submitted between 1994 and 1997 had major problems and 62% of these problems were caused by poor quality or missing data (Hill, Mitchell et al. 2000). In addition to critiques on the inherent difficulties of economic evaluation, some critics have challenged the application of HTA against its objectives (Birch and Gafni 2002); (Maynard, Bloor et al. 2004); (Williams and Cookson 2006).

Birch (Birch and Gafni 2002) believes that the objectives of NICE are not compatible with its selected methods. Maximising health gain from the use of NHS resources (technical efficiency), removing unfairness in the availability of technologies in different localities and minimising the possibility of further examples of unfairness or inequity being introduced (geographic inequities in the distribution of access to services) are important objectives of NICE establishment (NHS 1999), however, cost-effectiveness analysis (CEA) is invalid as a method of identifying programmes that maximise health gain from NHS resources and Incremental Cost-Effective Ratios (ICERs) are not available for all health programmes or technologies (Birch and Gafni 2002).

Selecting a trade-off between equity and efficiency is another subject which has attracted attention from some researchers. Maynard asked for more transparency on selecting between efficiency and equity and Williams believed that the HTA system had not done enough to achieve its equity objective. He believed that the HTA system needed more investment in developing better methodologies for managing equity-efficiency trade-offs (Maynard, Bloor et al. 2004); (Williams and Cookson 2006).

The mechanism of the decision-making process within NICE is another challenging subject. Although NICE has clearly delineated its criteria for decision-making, is stated that it depends mainly on the knowledge and experience of the Appraisal Committee. NICE has also formed a Citizen Council to ensure that its values resonate with public demand, but it has no specific legitimacy for determining the social values of the population (Rawlins and Culyer 2004). It would appear therefore that further clarification is still required. This may shift the challenge from the criteria for value judgements to the criteria for selecting committee members. In this case, the question would be who are the best people to appoint to the committee?

Though there are notable criticisms of the scientific methods of the health technology assessment, considerable numbers have targeted NICE's appraisal process. Freemantle showed that the effect of printed educational materials compared with no active intervention appeared small and of uncertain clinical significance (Freemantle, Harvey et al. 2000). Although HTA does more than providing printed materials (Stevens and Milne 2004), it may be beneficial for the HTA system to arrange a complementary plan to ensure that the result of the assessment section of the system (monographs), is applied to impact the behaviour of health workers within the system. However, the role of NICE is entirely different: NICE's appraisal process leads to a clear decision that will affect considerable numbers of individuals and stakeholders immediately. It is therefore reasonable to expect NICE to receive more consideration.

Irrespective of the fact that there is no evidence of impact of HTA, it seems clear that the system has an undeniable impact on the NHS in E&W (Stevens and Milne 2004). From a programme evaluation point of view, it is necessary to assess whether the programme is effective enough to attain its desired goals or benefits (Rossi, Lipsey et al. 2004). Assessing the impact of HTA is necessary to highlight its achievements in previous years. One of the notable outcomes of NICE is that it has accelerated the uptake of new and expensive technologies in England and Wales since its development and therefore has increased the NHS spending on new and cost-effective technologies. Thus it seems that it has met its pledge of faster access to new and effective technologies (NHS 1999).

Even with recent large increases in NHS expenditure, acute funding difficulties continue to emerge (Maynard, Bloor et al. 2004). Although NICE was not established to reduce or minimize NHS expenditure (NHS 1999) and is not responsible for NHS affordability (Rawlins and Culyer 2004); how much can the NHS afford NICE recommendations? And, if the NHS or DoH has to select from NICE recommendations, how can they do this? Thus it seems that NICE has no option but to consider a specific threshold for cost-effectiveness analysis based on NHS resources. Indeed, this is what has happened in practice; although in previous years NICE has denied setting any particular threshold for its judgement on the cost-effectiveness of health technologies.

Irrespective of challenges and concerns about the role and the process of the HTA system in E&W, it is one of the well-established, pioneers and complex systems in the world. Thus it is important to note what elements have made this system. It seems that three factors are important to note in the review of this system. On the other words these three elements play an important role to make the HTA system successful. The first factor is the structure and characteristics of the health system in the country. The central financing of the NHS provides the opportunity of controlling and managing the system clearly for the department of health and the treasury (Davies 2006). Centralized national health policy in the NHS, also, has important role for implementation of such national health

programme. The direct responsibility of the government in healthcare system and health challenges of the population put the NHS in one of the top priority of the government. And since it expects the programme improve the current situation of the health system, it supports the programme politically and financially.

The second factor is the structure and characteristics of the HTA system in the country. It is originated from the heart of the NHS research and development department; and at the same time, the process of decision-making is independent from the health department and the NHS. The values of the HTA system, in both assessment and appraisal sections, are also very important elements that have helped the system to increase its reputation and liability. The key values of the HTA system in England and Wales are accountability, probity and openness (NCCHTA 2007). The HTA system in the UK is accepted high ethical values of the NHS that are accountability, probity, and openness. Accountability means that everything done by those who work in the NHS must be able to stand the test of parliamentary scrutiny, public judgements on property and professional codes of conduct. Probity in the context of HTA system means that there should be an absolute standard of honesty in dealing with the assets of the NHS; integrity should be the hallmark of all personal conduct in decisions affecting patient, staff and suppliers, and in the use of information acquired in the course of NHS duties. The meaning of openness in this field is that there should be sufficient transparency about the NHS authority activities to promote confidence between the NHS authority or trust or its staff, patients and public.

One of the advantages of the HTA system is its openness to receive any topic from any individual, organisation or society. Though this may increase the numbers of unimportant topics, it also ensures that all potential sources throughout the country have equal influence in the identification of potential research topics.

NICE has actively engaged a patient and public involvement programme with lay membership in all NICE Committees and Advisory Bodies, the

Citizens' Council and through encouraging patent and public participation in the NICE consultation process.

The third factor that helps the HTA system in the country is the strong background of the research centres and institutes in the country. This has helped the system in both supporting and critiquing it simultaneously. There are numbers of research groups and research centres that are undertaking research projects regarding the health technologies (Table 7.2).

Table 7.3 shows elements involved in HTA and compares the UK and Iranian systems.

Table 7.3 Elements of a HTA system; a comparison between E&W and Iran

Factor in HTA	UK system	Iranian system
Healthcare Delivery System	Family doctor and referral system	Free and unlimited access, no referral system
Health Care Financing	Tax-based	Mixed, mainly health insurance based
Research Centres	Very good	Not bad
Human Resources (e.g. Health Economists)	Very good	Highly restricted
Data Sources	Very good	Not bad
Financial Resources	Very good	Limited

7.5 Applicability of HTA to Iran

As discussed in Chapter 2, HTA has developed from single technology assessment to service delivery assessment and prioritisation of the healthcare system (Banta and Behney 1981[a]; (Banta and Luce 1993);

(Battista 2006). This growing breadth brings particular attention to the concept of policy-making. This attention draws HTA closer to the political environment in which decisions are made. As HTA is receiving increasing attention, the adaptation of a HTA system to its context becomes highly important.

The aim of this section is to identify and discuss a potential HTA system for Iran considering the structure and the challenges of the Iranian health system and comparing the structure of the health system and HTA in E&W.

To operate a HTA system successfully within a health system, two important steps must be considered; firstly, the provision of quality HTA and secondly, implementing HTA results effectively to influence health workers' behaviours. Two crucial elements therefore must be focused on; the *products* or results of HTA, and the *process* of the implementation of the results. In the following sections, the important factors for a potential HTA system in Iran are identified, discussed and compared in stages with the HTA system in E&W.

7.5.1 The aims and objectives of a potential Iranian Health Technology Assessment programme

The aims and objectives of a HTA system influence its design, methods and even its implementation processes. It is important therefore to clarify the aims of a HTA system before its establishment. Whether the HTA system will improve the quality of healthcare services; whether it is expected to increase the efficiency of the health system and to offer value for money; cost containment within in health system; or to increase equity in healthcare delivery. It is also possible to combine objectives, but it may be necessary to define a trade-off between, for example, equity and efficiency.

Various responses to such questions may result in difference structures and processes. It is important to note that the answers to such questions reflect the values and attitudes of both the health system and society and the solutions, therefore, may not be straightforward.

As clearly demonstrated in earlier chapters, the review of the interviews news and other distributed materials indicate that equity is one of the top priorities of health system in Iran (Dr Pezeshkiyan). Efficiency is also considered significant by healthcare managers and health policy makers (see Chapter 4). Selecting a trade-off between equity and efficiency is therefore one of the crucial steps in the establishment of a HTA system in Iran.

The question must be raised as to whether Iran would benefit from HTA in single health technology assessment, clinical outcomes assessment or policy-making and prioritization in the health system. Considering the present context of HTA in Iran, it seems that the aims of a HTA system in Iran must be a combination of all of these elements. To illustrate, a HTA system in Iran could help decision-makers to decide on single health technologies for including/excluding new pharmaceuticals. HTA could also be used to evaluate clinical outcomes within the health system. The application of HTA in prioritising healthcare may also help policy-makers to focus on the most important activities and policies for the population and increase the health gains of the society with limited resources.

However, HTA is not the panacea for all healthcare challenges. It could help decision-makers and healthcare managers (Banta and Luce 1993) and therefore improve the efficiency and quality of healthcare services (Banta and Luce 1993); (Battista 2006), but only if it is carefully designed and takes into account all contributing factors and results are implemented effectively and properly. It is crucial therefore to discuss the details of the HTA system in the context of the present situation in Iran as well as the future.

7.5.2 Potential type of Iranian HTA

Two general types of HTA systems currently exist in various countries. The first type is HTA for providing information and knowledge with the hope that such information will be used by health workers to improve efficiency and quality of health services. One of the good examples of such system is the HTA system in the USA. The second type of HTA system are those that do not leave the results of HTA just for publication, rather they use the results, together with other evidences and experiences in healthcare delivery services as well as healthcare management and policy making. A good example of this type of a HTA system is currently active in the UK.

Many studies show that publication and dissemination of HTA results without a clear implementation process will not change the behaviour of health workers significantly. In addition, as it is examined in Chapter 2, although the main purpose of HTA is to provide objective information to support healthcare decision and policy makers at national, regional and local levels (Banta and Luce 1993); (Battista 2006), in some countries HTA agencies are not limited simply in providing information for health decision-makers, rather they become themselves a part of decision-making. The HTA system in E&W is one of the clear examples of such system. The National Institute for Health and Clinical Excellence (NICE) is indeed one part of the decision-making process.

These studies encourage establishing the latter model for Iran. Furthermore, current challenges of Iranian health system could even further decrease the incentives of health workers and other stakeholders to apply the results of HTA in their health activities. This could more likely happen in situations when application of HTA results leads to some conflict between the benefits to various parties in the healthcare market. For instance, if the results of HTA confirm that a new and expensive technology for cancer treatment is cost effective, doctors will encourage prescribing it and patients will expect their insurance providers to include the drug in their insurance policy. This is while the health insurance organisation may claim that they are not able to afford it and therefore to

cover it. Such interest conflicts would increase confusion of the patients and would result finally in a greater decrease in the quality of care and in the health of the society. It would appear therefore that the health system in Iran needs a HTA system that places both production and practice parts together.

In addition, it is also important to note that, as it is explained in Chapter 4, the Iranian government have direct responsibility to provide reasonable healthcare services for all individuals of the society. Thus the government can not be neutral regarding the health technology challenges of the health system and, in consequence, to HTA programme. It is expected therefore that the government, and in particular, ministry of health would support a HTA system that would help to improve the quality of care and to reduce some of present challenges of equity and efficiency in health system. It would appear therefore that the second type of the HTA systems is most appropriate for Iran.

7.5.3 Administration and structure of potential Iranian HTA

Before discussing this subject, it is necessary to separate the *production* section of HTA system from the *process* of implementation and decision making about HTA system. The purpose of this part is to discuss the administration and structure of HTA system. It is clear that production section of the HTA would carry out within the universities and research groups.

Battista stated that the organizational structure of HTA agencies is not very important, rather the ability of the organisation to put the four features of HTA (including scientific integrity, links to multiple stakeholders, timely and accurate dissemination of assessment results) into practice is essential. However, while this could be true in providing quality HTA results, it is highly debatable when considering a HTA system that is expected to bring the results of the HTA into practice. The production of HTA results is a sophisticated academic work and must be

done in university based research centres and research groups. What is important in this part is where to place the executive part of the HTA system.

It seems that the organisational structure of executive part of HTA system is important firstly to provide an acceptable level of association and cooperation with all healthcare stakeholders within the health system; and secondly to keep its independency from political, social, and financial influences as much as it is possible, and thirdly to make a balance between different interested parties.

Universities and research centres in Iran seem to have little capability to run a HTA system, at least at the time being. This is because, first of all, there are not sufficient numbers of academic experts to undertake this work (limited human resources). Secondly, the establishment of academic courses and developing international cooperation requires time, financial resources and appropriate level of governmental supports (limitation of financial and legal supports). The third reason is the current circumstances and difficulties that the Iranian health system is facing, as is discussed in Chapters 4-6. These challenges made it almost impossible to implement HTA results successfully without strong political power. It would appear therefore that the university-based HTA system is not appropriate for Iran.

The next issue is where to place the HTA system within various parts of Iranian health system. Should it be placed in Food and Drug Department? Should it be placed in Therapeutic Department of the ministry of health? Or it should be placed in health insurance organisations? There are some reasons in favour of each of them. As pharmaceuticals have been the health technologies most commonly assessed, one may believe that Food and Drug department is the most appropriate place for establishing a HTA system. But, since the HTA is not limited only to drugs and can embrace other health devices and technologies, it could be justified that the Therapeutic department within the Ministry of Health is a more appropriate place for HTA system. From another side, taking into account

that the structure of health system in Iran which is very close to insurance base, there is a case that the HTA programme should based within the health insurance organisations.

The last argument seems more logical than others. Health insurance organisations are the main organizations that are losing their resources due to lack of clear guidelines in the utilisation of new and high cost technologies. In addition, they have numbers of difficulties for including or rejecting health technologies from their insured services. Nonetheless, the analysis of health insurance policy and health insurance organisations confirmed that, at least at the time being, this is difficult for these organisations to undertake this critical mission and responsibility. The first reason for this is that the most health insurance organisations in Iran are not independent organisations financially and structurally; they have strong link to the government (see Chapter 5). And so they are not completely free to establish and improve a comprehensive HTA system. Secondly, health organisations do not have sufficient authority to implement the results of potential HTA within the health system. At best, they can only recommend those doctors, hospitals and other healthcare providers that have contract with them to follow the HTA results. It is noticeable that, as discussed in Chapter 5, considerable numbers of people have no insurance coverage and some healthcare providers and specialists also do not have contract with any health insurance organisations. The implementation of HTA results would not able therefore to improve overall quality, efficiency and equity of healthcare services extensively. The third point is the various levels and the degrees of financial resources and policies between the main HIOs. These differences may lead to dissimilar evaluation criteria and threshold setting for economic evaluation of the health technologies and then different guidelines and advice. The results of such variation could lead to different level of services and activities which would not improve the quality and efficiency of services very much and would not help equity in health after all.

It would appear, therefore, that a governmental-based HTA is most appropriate programme for Iranian health system, rather than health insurance-based programme. Thus it seems that the best place for an effective HTA system is within the structure of ministry of health. This would help the new-established system to be supported in all of its aspects and dimensions including politically, financially and legally. However, as HIOs now placed under management of Ministry of Welfare and Social Security (MW&SS), it is necessary for HTA system to be supported by both MH&ME and MW&SS equally. It is also very important to be aware of the influence and the impact of government on the production and the process of HTA results. The determination of the details of the system needs further research.

There are considerable number of tasks and activities that are necessary to be done before and during the establishment of a effective HTA system, which require strong and full supports of the government at each level. The details of requirements in production of quality HTA and implementation of the results of HTA in macro, med and micro levels are discussed in next section.

7.5.4 Production of high quality HTA

Production of high quality HTA is the first key tasks of all HTA systems and is common in both types of HTA systems; HTA for production and HTA for implementation and policy-making. As production of quality HTA is related to some requirements and conditions in various levels, the details of these requirements are discussed in macro, med and micro levels.

7.5.4.1 Evaluation at the macro level

Convincing decision makers and high authority individuals within the system for development of a HTA system is the first job at the macro level. This job itself will need preparation of some written documents and oral presentations to describe the aims and objectives of a HTA system and its potential benefits for the Health System. Irrespective of this fact that achieving macro-level agreement and support is one of the easy

tasks amongst other parts of requirements for establishment of an effective HTA system (Battista, R. 1999), many health policy makers in Iran are aware of the benefits and helps of HTA in general, as it was clear from the interviews.

The next job at this level is achieving approval for establishment of relevant educational courses and resources to promote and distribute the concepts and knowledge of HTA, health economics, evidence-based medicine and other relevant materials. This should include formal and financial support of the educational courses. International cooperation and exchange of expertise and students could be part of this. This matter is very important particularly at the beginning of the establishment of educational courses.

7.5.4.2 Evaluation at the med level

As soon as there are some individuals who are ready to undertake HTA projects, providing details of HTA process become important. If the HTA system is to provide some health guidance or guidelines for applying within the health system, as is happening in E&W, the details of HTA process become very important. In this case, it is important to determine who, how and when to select the topics for assessment.

It is reasonable to expect that individuals, organisations and departments who are paying for health services are interested parties to select topics for assessment. This is why in E&W, for example, the National Health Service is involved in topic selection for HTA (see the first part of this chapter). Likewise in insurance-based health systems, like Germany and the Netherlands, health insurance organisations are actively involved in topic selection for HTA. As has been discussed in Chapter 5, although health insurance organisations are the main customers of healthcare services, the real payers of healthcare services are mainly the government and the patients, because of some supportive and subsidies policies for various groups of the society (see Chapter 4). Health insurance organisations also have limited resources and numbers of responsibilities

that will make them want to play an active role in the process of decision making in HTA system. It seems therefore a "topic selection committee" including representatives of health insurance organisations and ministry of health would be able to take into account all stakeholders benefits and costs under one umbrella.

Determination of the process of quality and robust HTA as well as the procedure of bringing them to practice is vital in achieving a successful HTA system. As the contextual consideration is necessary for establishment of a HTA system (Battista 2006), it is also worth to take it into consideration in designing HTA process and procedure. There are numbers of elements that support contextual consideration in HTA process. Economic differences between countries and its impact on threshold setting in economic evaluation is one of the first and important elements. Social and cultural values also play an important role in this field. There are numbers of examples that confirm that while the clinical and economic evaluation of some specific drugs, say in cancer treatment, do not support the utilization of the drug, social pressures and moral obligations force insurance providers and health systems to provide and support its consumption, e.g. Riluzole in the UK. Differences in health system priority are the third element that supports contextual consideration in the process of HTA. That is numbers of non cost-effective technologies might get utilisation support to achieve the specific priority of health system for a period of time. National priorities and strategic objectives are the fourth element that could affect the criteria of decision making in HTA system directly or indirectly.

It seems that establishment of NICE in 1999 was a first step to focus on local social values and health priorities, rather than just scientific judgements and information. Though NICE has received many consideration and critiques in its criteria for approving health technologies (Birch and Gafni 2002); (Maynard, Bloor et al. 2004); (Williams and Cookson 2006) it would appear that considering appraisal process together with assessment procedures could increase the stability, reliability and consistency of the HTA system with health system and the

whole society (Stevens and Milne 2004). The HTA system in Iran, also, could benefit from appraisal process in parallel with the assessment part. This is notable that while international collaborations are helpful and practical in assessment part, the appraisal section should mainly carry out by local healthcare managers and experts.

Providing a clear list of criteria for topic selection is the other important point in this level that has at least three advantages. The first advantage of having such list is that this could provide clear, precise and explicit role for committee members who are responsible for topic selection. The second advantage of the list is that it would be a good document for critiquing and therefore for future improving. Increasing and strengthening the trust and confidence of all healthcare providers and consumers to the system is the third and also very important advantage of providing criteria list for topic selection.

7.5.4.3 Evaluation at the micro level

Since all HTA results, guidelines, and health policies would be based on what will be provided at the micro level, this level is extremely important. The existing and availability of primary data are categorised in micro level elements of the provision of quality HTA production. These factors are crucial for running a successful HTA programme. This is because the rest of HTA system is based on them.

Comparing situation of existing and availability of strong, valid and reliable databases in Iran and E&W, it is understandable that relevant databases in Iran are not as strong as in E&W. Nonetheless there are numbers of valid, strong and rich databases in Iran which generate and collect various types of data including health associated and economic data. The Iran Statistical Centre and Central Bank of Iran have important available databases about wide range of health related data in Iran. However, there are serious concerns about the existing or availability of micro data in different levels of health system and health technologies in Iran. Reliable and easy access to data could encourage researchers to use

and analyse them in order to undertake research in the field of health and healthcare services. Creating some new databases about different levels of health system including hospitals, health insurance organisations, numbers and various types of patients, and details of health expenditures would be therefore a key step forward in this level.

The availability of data for researchers has, also, an equal importance in this level. Both difficulties, lack of primary data and unavailability of existing data, exist in various degrees, at the present. The provision and collection of some relevant data for this research project is one of the clear examples of these difficulties.

7.5.5 The effective model of implementation of the HTA results

All investments in provision of quality HTA results would improve the quality, efficiency and equity of healthcare services "if" an objective and effective model of implementation is undertaken. Like the process of production of quality HTA, the process and elements of implementation model also involves macro, mid and micro levels. The requirements and conditions of effective model of implementation in these three levels are discussed in this part.

7.5.5.1 Evaluation at the macro level

The experience of HTA systems in various countries confirms that legal, political and financial supports are important macro elements that could influence the probability of success of a HTA system directly (Oliver and Mossialos 2004); (Orvain, Xerri et al. 2004); (Stevens and Milne 2004). The systematic support of HTA implementation is in fact an important distinctive feature between HTA for publication and HTA for policy and implementation.

Legal support is one of the key elements that could provide more power for implementation of the results of the HTA system. This is particularly important when HTA system is going to stop or limit the utilization of one

or more specific health technology that reduces social, economic and even metaphysical benefits of one or groups of companies or individuals directly or indirectly. Legal support could be achieved through legislation and regulation. In Iran this could be provided via ratification by the cabinet or parliament.

Political support, also, would increase the executive power of HTA system in practice. This support is particularly important against some powerful providers and traders of high cost technologies.

Without financial support it is extremely difficult to run a successful HTA system. This point is important because the establishment of HTA system may increase health expenditures through recommendation of high cost, but cost-effective, technologies. This could happen if the aim and objectives of HTA system is defined as "increasing the quality and efficiency of health services", rather than as "cost containment in health services".

One of the elements that made the HTA system in E&W successful (Stevens and Milne 2004) is that this system benefits from all of three mentioned supports during its activities. The assessment part of the HTA system (HTA Programme) is within the Research and Development department of the NHS and therefore, in theory, should enjoy NHS support directly. Although NICE is an independent professional body in its structure, its activities are supported by the Ministry of Health. The implementation of NICE guidance is compulsory, according to ministry of health regulation. Likewise the NHS is given three months time to provide appropriate amount of financial resources for implementation of NICE guidance.

Considering the overall challenges of the health system in Iran, this would appear that the HTA system needs full economic, legal and political support to play an effective role within the health system.

7.5.5.2 Evaluation at the med level

As it was discussed before, simply publishing and distributing of the HTA results doesn't lead to behaviour changes; therefore it is necessary to find a procedure to bring these results to practice. Having an effective healthcare management system is one of the key elements to a successful implementation procedure in HTA system (Banta and Vondeling 1994); in fact, the more successful the healthcare delivery system, the more effective the HTA system. There are some suggestions in Chapters 4-6 about the required reforms that may improve management of the Iranian health system. However, in addition to effective healthcare management system, the HTA system needs to have a clear, accurate and effective implementation process; though the implementation process could be transferred to the healthcare management system. There are three main questions in this part. First, how is assessment evidence to be assembled, synthesised, and disseminated so that appropriate policies on technology may be formulated and executed?

In E&W, NICE is responsible to prepare three various productions using the results of assessment part within the HTA system. As it is discussed in part 7-4 of this chapter, the help of NICE in the HTA system is to address social values and policy issues in decisions about health technologies. In spite of some critiques of NICE's methods and processes of appraising health technologies, the HTA system in E & W benefits from NICE works in improving the quality of health services as well as improving the behaviour of health workers across the countries. Nonetheless, NICE is also improving and developing its methods and its processes continuously in response of some internal and external reviews of its job. It would appear therefore that establishment of an Iranian version of NICE could help Iranian HTA system in considering textual circumstances in its recommendations and decisions.

The second question is how produced guidance and guidelines can be implemented in the diffusion and utilisation of healthcare technologies? This part of the HTA is undertaken within the health systems and needs

therefore a close cooperation of the healthcare managers. Besides guidance and guidelines, NICE also provides practical guidelines to describe implementation process in various levels. Providing details of implementation process could offer the opportunity of applying it in the least time and with the lowest cost. This may also provide a framework for future evaluation for measuring the degree of implementation success.

The third point in this part is to see whether the current system of organizing, financing and delivering healthcare services help or hinder the processes of HTA implementation? Although there are some similarities between Iranian health system and the NHS in the UK, there are also significant differences between the two in this part. Similarities of the two systems are in various levels of management system as well as central health policy formulation and administration. The essential difference, which affects the HTA implementation process directly, is the financing of the system. In contrast to the UK, the Ministry of Health does not have direct and strict control on health expenditures of the system, rather the health insurance organisations do. Health insurance organisations therefore could and should play an important role in this part. They may link their reimbursement policy to the implementation of the HTA results to encourage various types of healthcare providers to follow the HTA productions. Since there are four main health insurance organisations in Iran, this is highly important for effective health technology management that all of them cooperate with the HTA system in a same manner. However, it is important to note that almost none of them are completely an independent organisation, since the Ministry of Welfare and Social Security (MW&SS) was established in 2005. From that date all managerial and financial affairs of health insurance organisations from the Ministry of Health shifted to MW&SS, which has power to ask them to follow the HTA productions.

7.5.5.3 Evaluation at the micro level

What finally doctors, specialists and other health workers should do at the final points, doctors' offices, health centres and hospitals, are placed in

micro level. There is no doubt that the end point is very important. This is obvious because the results of all of scientific, managerial, social, financial and political efforts are expected to be translated into practice at this point.

Comparing health systems of Iran and E&W, as the context of HTA system, there are three essential differences between Iran and E&W in this level that influence the utilization of health technologies and consequently the implementation of HTA system (Table 7.1). To have a successful and effective implementation process, this is necessary to consider these differences and taking a practical and appropriate design for the programme.

The first dissimilarity is in the structure of healthcare delivery system. While patients in E&W receive their care from GPs (family doctors) and refer to specialists and hospitals in further needs of cares, Iranian patients can be visited by any doctors and in any time without specific limitation. They can also go directly to specialists to discuss their health problems (see Chapter 4 for more details).

Healthcare financing is the second difference between Iran and E&W in this level. While Iranian patients have direct financial relationships with their doctors, patients in E&W do not. GPs and specialists in E&W, therefore, prescribe new and expensive health technologies, mainly, based on their own beliefs on effectiveness of new drugs (Prosser and Walley 2006) and the patients have little power to request specific drugs or diagnostic technologies.

Health cost coverage is the third difference in micro level process of HTA system. Whereas almost all of UK residents benefiting from health cost coverage, considerable numbers of Iranian population do not. This element could influence the prescribing in a negative way. That is patients who don't have any health insurance coverage may also have difficulty for paying high cost drugs or other health technologies.

Two first elements encourage utilisation of health technologies inefficiently, particularly at the level of general practitioners. Considering the surplus numbers of doctors in large and well-off cities in Iran and positive competition for attracting more patients (Chapter 4), it is necessary to carry out additional activities that help HTA results to be effective.

The lack of effective health cost coverage in Iran could increase financial inequity, inequity in access to healthcare services and finally inequity in health seriously (Chapter 5). The effective implementation of HTA results could improve the overall equity of the population. Though this element shows how important is the implementation of HTA results within the Iranian healthcare services, this also requires designers and managers of HTA system to be aware of the specific circumstances of all groups of the population.

7.6 Challenges and opportunities

It is quite understandable that establishment of a HTA system will cause a significant change to the current health system and needs therefore to be considered thoughtfully. Like many radical improvements (Grayson 1997), HTA needs to be well understood within various types of stakeholders before it come to face the numerous practical difficulties of changing attitudes and behaviour. Thus, it would appear that taking into account every detail of a comprehensive, stable and internally consistent HTA system may take a number of years to be established. While it is important to design a comprehensive, stable and internally consistent HTA system, it is, also, important not to delay in using a HTA programme too much. It might be beneficial, therefore, to consider two development plans for establishment of a HTA system; primary and comprehensive. Although describing details of a primary establishment plan needs further independent research, it could include an international cooperation for undertaking assessment for most important topics of current system. The

noticeable point is however that the short and primary plan should be in the same direction of the long term programme.

All countries are facing the same basic problems that are addressed by HTA. No country is able to meet all of the demands for healthcare made by all of its population. Thus, health technologies have to be evaluated for clinical and cost-effectiveness in order to prioritize its use within national health systems. Establishing a comprehensive and high quality system of HTA is crucial to achieving this objective of healthcare policy in each country.

Given the similar objectives shared by each country, it is important that countries considering or in the process of establishing structures of HTA (such as Iran) are able to learn from the experiences of countries that have more established systems of HTA. A range of international agencies have been established to facilitate such international transfers of knowledge, experience and expertise both on a bilateral and a multi-lateral basis. However, whilst acknowledging the importance of international co-operation in helping to establish structures of HTA in 'new' countries, it remains vital that the ultimate structure is developed with due regard to the culture and expectations of the population being served.

Irrespective of primary plan, the next step for the establishment of a comprehensive and stable plan is convincing health policy and health decision makers that a HTA system may better enable healthcare system at both the strategic and operational level to improve effectiveness, efficacy and equity of the system. As Battista stated (Battista 2006), considering the requirements for a successful HTA system in three levels of macro (policy makers), med (institutions), and micro (practitioners and patients), it would appear that the requirements in macro level are easier to achieve, compared to the other two levels. However this doesn't mean at all that there is no challenge or difficulty at this level, also.

There are also some practical and technical difficulties that healthcare managers and policy makers might face in trying to practice HTA. In

addition to inherent technical challenges in economic evaluation, evidence-based medicine, and appraisal methods, the potential resistance of some powerful medical groups against HTA system is predictable. As discussed in Chapter 4, overcoming traditional medical domination, particularly in some specific professional fields, is not easy and needs careful management.

Cultural acceptance of HTA values and objectives could play an important role in running a successful HTA system in Iran. This is partly because numbers of current challenges and difficulties of healthcare delivery system is rooted from wrong beliefs and bad health behaviours (see Chapter 4 for more details); and partly because acceptance of HTA values and objectives could facilitate the consequent changes and alteration of the healthcare delivery system. Rejection of HTA values from population and medical workers may increase dissatisfaction of the professionals and population from the system and finally lead to breakdown of the system.

Nonetheless there are positive points and opportunities that also need to be considered. Equity (justice) and efficiency (the best usage of resources) have been amongst strong social, cultural and even religious values of almost all Iranians from a long time ago. Consideration of the Islamic Republic of Iran to distribution of equity is highly important as the second act of the Iranian institution urged the government to distribute justice in all features of human life (Revised Iranian Institution, 1989). As is explained in Chapter 4, the minister of health (in 2004) also stated that "equity is the first priority of the Health System" (Pezeshkiyan, 2004). These are good starting points that could help policy makers to explain and justify the values and objectives of the HTA system and its consistency with social values of the society.

Thus one of the positive advantages that facilitate HTA establishment in Iran is the consistency and equivalency between values and objectives of HTA and social, cultural and even religious values of the society as well as the government. In fact HTA could be applied as a tool to bring the values of the society, i.e. equity and efficiency, into practice.

7.7 Conclusion

The HTA system in E&W is benefiting from a good structural context (the NHS), great academic and research centres, and strong legal and financial support. These elements have had considerable impact on its function. Considering the lessons from the HTA system in E&W and current situation in Iranian Health system, it is now clear that a HTA system can be of a great benefit *"if"* it is established carefully and based on its context. While it is good and reasonable to benefit from the HTA system in E&W, considerable attention should be paid to similarities and differences between the two contexts.

It would appear that following strategies could increase the impact of the potential HTA system on healthcare system in this level. The first and highly important strategy is to undertake the recommended health system reforms that are suggested in Chapters 4-6. The second element is to discuss and explain the role and potential benefits of a HTA system with health policy makers (macro level), particularly those who may benefit more from establishment of a HTA system; which are health insurance organisations and the department of health. This could be done through face to face communication, written documents, general presentation or reasonable combinations of them. The next steps at med and micro levels should be done with the help and support of health policy makers. Good and close cooperation of different departments, including health insurance organisations and health care delivery system, are highly important in applying an effective HTA system.

Providing some general educational material targeting ordinary population seems, also, a valuable strategy to inform the benefits and advantages of HTA recommendations for the population. Public teaching could improve understanding of the public regarding the aim and the objectives of HTA. This could increase the acceptability of the HTA results for the end users of the health services. Furthermore, such information could adjust their expectations from new and expensive health technologies and then may

lead to positive behavioural change and social support for HTA implementation.

CHAPTER 8

CONCLUSION

8 CONCLUSION

8.1 Introduction

Health services in Iran, like many countries across the world, have faced a wide range of challenges in recent decades. Demand and costs have expanded due to the introduction of a range of expensive treatments and technologies, aging populations and increasing public demands and enhanced patient expectations (Carlsson, Hultin et al. 1998); (Henderson 1999); (Walley, Haycox et al. 2004); (Donaldson, Gerard et al. 2005). The root of these challenges lies in the mismatch of enhanced demand for healthcare compared with the limitations placed by the Iranian government on available resources on the other. HTA has been effective in many countries to increase efficiency, equity and effectiveness in healthcare systems (Banta and Perry 1997) but it is important to acknowledge that the HTA systems applied in each country display a wide range of differences. The root of these differences lies in the context in which they are being applied in their health systems (Banta and Vondeling 1994) and their socioeconomic status (Battista 2006). It is therefore impossible to design and implement an effective HTA system for Iran without a detailed contextual analysis. As discussed in Chapter 1, the logic of the method utilised in this study is based on a needs assessment. The answers to the questions raised in Chapter 1 are presented here.

8.2 Current situation of the health system (current problems)

8.2.1 Healthcare Delivery System

Considerable numbers of challenges and difficulties facing the Iranian healthcare system were addressed in Chapter 4. Many of these challenges arise from structural difficulties and they need to be clearly addressed by structural reforms. The lack of an effective primary care system and the lack of clear stratification between primary and secondary healthcare services were amongst the most crucial difficulties addressed. In addition

to these structural difficulties, there are also a range of policy challenges in the system which must be addressed with some urgency. The lack of therapeutic guidelines and the lack of clinical and economic assessment of new technologies before their implementation are amongst the most important policy issues in improving the healthcare delivery system in Iran.

8.2.2 Health insurance system

In a similar manner to the healthcare delivery system, the health insurance system in Iran is confronted by a range of structural and policy issues (Chapter 5). The existence of parallel organisations with similar aim and objectives leads to crucial difficulties that have resulted in considerable waste of resources and duplication of services. Such issues have decreased the efficiency of the system significantly. The lack of systematic and comprehensive methods of evaluation for introducing or excluding new health technologies has led to huge demand for new technologies to be introduced and limited resources with which to fund such introductions. These challenges have decreased the function of health insurance system in Iran significantly and it is questionable whether the current health insurance system is the best available services for the population of Iran. Unfortunately, there is insufficient evidence either from the literature or the interviews to make any definitive statements with regard to this issue.

8.2.3 Pharmaceutical system

The situation faced by the pharmaceutical system reflects that affecting other parts of the Iranian health system (Chapter 6). The main challenges facing the pharmaceutical system arise from a range of policy issues. The Food and Drug Department (FDD) confronts the main problem of achieving efficiency and equity while simultaneously supporting the pharmaceutical industry's development. From the results of the interviews and analysis of the Iran National Drug Policy, it is clear that the FDD has not developed a clear strategy to address and trade off these objectives.

This leads to uncertainty both for the consumers of the pharmaceuticals as well as the domestic pharmaceutical industries.

8.2.4 Summary of Part I

From the discussion and literature reviewed in earlier chapters, it is clear that:

- Iranian health system is suffering from the structural difficulty in healthcare delivery system
- There are considerable numbers of policy issues in Iranian health system
- The effective function of health insurance system in Iran is seriously under question
- Health Insurance reimbursement is not based on HTA
- There is no clear pharmaceutical policy in achieving efficiency-equity as well as industry development
- Health technologies (especially drugs) are often accepted for general use without evaluation
- Health technologies are often over-supplied relative to the estimates of health needs of the population
- Health technologies that have been evaluated and accepted for use on the basis of the evaluation, are often utilized for conditions beyond those covered by the evaluation
- Health technologies that have been evaluated and accepted for use are used at frequencies and for conditions beyond those known to be efficacious and necessary

8.3 The causes of the problems

There are numbers of explanations for the problems affecting sections of the Health System in Iran. Such causes are discussed in detail in the appropriate chapter and here the aim is to assess whether it is possible to find one or more common cause/s for each of these problems. Almost all of challenges and difficulties originate from non-evidence-based decision

making. Decision-making appeared to respond to pressures of various kinds and it was rare that there was evidence to support the new decisions. For example, stopping the normal increase in medical tariffs in 1980s seems to be simply based on the belief that "the medical workers are rich enough" (Chapter 4). Separating medical universities from the other universities and merging the medical education system with the healthcare delivery system simply based on the belief that "merging medical education and healthcare delivery system will increase the benefit of both medical education and healthcare delivery system through sharing the facility and education environment" (Larijani, Marandi et al. 1996). Other examples were, increasing the numbers of medical students, implementing "hospitals' self-management scheme" (Chapter 4), development of the Ministry of Welfare and Social Security (Chapter 5), and opening doors to foreign pharmaceuticals (Chapter 6). What is common for all of these policies is the lack of evidence that their implementation would lead to improvements in the ability of the Iranian healthcare system to meet more effectively the need of its population.

8.4 The potential solutions

Many of the challenges and difficulties in the Iranian Health System exist in other health systems across the world more or less with the same form. As discussed in Chapter 2, HTA emerged as the result of increase in healthcare and pharmaceutical expenditures (Feeny, Guyatt et al. 1986); (Banta and Luce 1993). HTA currently plays an increasingly important role as a key tool to improve the management of limited health care resources in a wide range of countries (Banta and Perry 1997); (Battista 2006). The HTA system in England and Wales is one of the most well developed and complex HTA systems in the world. Reviewing this system showed that a HTA system could help health decision-makers to confront difficult rationing decisions on a more rational basis. Although currently there is no evidence confirming the impact of the HTA system on NHS services, it seems apparent that the system has led to significant benefits for the NHS in E&W (Stevens and Milne 2004).

8.5 Final words: Would the Iranian health system benefit from the development of a HTA programme?

Given the context of the Iranian health system, it seems that the development of a HTA programme in Iran would enable the healthcare system at both the strategic and operational level to improve its effectiveness, efficiency and equity. However, it is important to acknowledge the limitations inherent in the analysis undertaken in this thesis. Given the limited evidence available in either the published or 'grey' literature, it was inevitable that new sources of information had to be generated through undertaking interviews with key informants. However, such informants will inevitably reflect their own personal views in their responses which may be at odds with either reality or the prevailing perceptions of their peers. As far as possible, any individual biases have been eliminated through the process of triangulation of perceptions of different interviewees in an attempt to identify a consensus on the important issues being addressed in the interviews. Given the limited number of interviews undertaken, however, it is highly likely that certain individual biases and perspectives will remain.

This thesis has undertaken a detailed analysis of the structure, function and associated policy considerations affecting the Iranian health system. The analysis has emphasised the potential ability and function of HTA programmes to assist the Iranian health system in confronting a range of challenges. Such challenges include:-

- HTA would assist in developing and implementing clinical guidelines to improve the effectiveness and the efficiency of the system
- HTA would assist in directing resources for new health technologies to ensure their clinical and cost-effectiveness prior to dissemination
- HTA would assist the health insurance system to operate and use their resources more effectively

- HTA would assist the Pharmaceutical system to direct its resources more effectively by adding cost-effective drugs to the Iranian Drug List
- HTA could help policy makers to directly address policy trade-off and establish an explicit priority list for national health programmes

However, as emphasised in Chapter 7, HTA needs to be acceptable and supported by a wide range of stakeholders prior to its implementation. It must address the numerous practical difficulties involved in changing attitudes, behaviour and expectations of patients and Iranian society. HTA is not a panacea to solve all of the healthcare challenges facing Iran but must be integrated into the structure of health services as an integral element of an overall health policy. However, development of evidence-based decision making, rather than pressure-based decision making, combined with a range of necessary structural reforms would undoubtedly help the Iranian Health System to perform more effectively to the benefit of all Iranian citizens.

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